MEDICARE PRESCRIPTION DRUG BENEFIT

Solicitation for Applications from Prescription Drug Plans (PDPs)

January 21, 2005
(as Revised on March 9, 2005)

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1. GENERAL INFORMATION

1.1 Purpose of Solicitation

The Centers for Medicare and Medicaid Services is seeking applications from qualified entities to enter into a contract to offer Medicare Prescription Drug Plans (PDPs) as described in the Medicare Prescription Drug Benefit Plan Final Rule as published in the Federal Register. Please submit your applications according to the process described in Section 2.0. If you are planning to apply you must submit a notice of intent to apply as described in Section 2.4.

1.2 Background

The Medicare Prescription Drug Benefit program was established by section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and is codified in section 1860D-1 through 1860 D-41 of the Social Security Act (the Act). Section 101 of the MMA amended Title XVIII of the Social Security Act by redesignating Part D as Part E and inserting a new Part D, which establishes the Voluntary Prescription Drug Benefit Program (hereinafter referred to as "Part D").

1.3 Objectives and Structure

The new Part D benefit constitutes perhaps the most significant change to the Medicare program since its inception in 1965. The addition of outpatient drugs to the Medicare program reflects Congress' recognition of the fundamental change in recent years in how medical care is delivered in the U.S. It recognizes the vital role of prescription drugs in our health care delivery system, and the need to modernize Medicare to assure their availability to Medicare beneficiaries. Effective January 1, 2006, the Part D program establishes a optional prescription drug benefit for individuals who are entitled to Medicare Part A and/or enrolled in Part B.

In general, coverage for the new prescription drug benefit will be provided predominately through private at-risk prescription drug plans that offer drug-only coverage, or through Medicare Advantage (MA) plans that offer integrated prescription drug and health care coverage (MA-PD plans). PDPs must offer a basic drug benefit. MA-PD plans must offer either a basic benefit or broader coverage for no additional cost. Medicare cost plans and PACE organizations may, at their election, offer a Part D drug plan in the same manner as an MA-PD plan. If the MA-PD plan meets the basic requirement, then it may also offer supplemental benefits through enhanced alternative coverage for an additional

premium. For cost plans, even for the basic Part D benefit, the drug benefit will be a supplemental benefit.

Applicants who offer either a PDP or MA-PD plan may offer national (i.e. offering a plan in every region) or regional plans. MA-PD plan applicants may also offer local plans. CMS has identified 26 MA Regions and 34 PDP Regions, not including territories, in which PDPs or regional MA-PDs may be offered. Additional information about the regions can be found at http://www.cms.hhs.gov/medicarereform/mmaregions.

The MMA requires that each region have at least two Medicare prescription drug plans from which to choose, and at least one of those must be a PDP. In areas where the required minimum number of plan choices is not available, the MMA requires CMS to contract with Fallback Entities. Fallback Entities must satisfy the same requirements as PDPs, but will receive reimbursement for drug costs from CMS on a cost rather than a risk basis. This solicitation is only for entities seeking to operate a PDP. Separate Part D solicitations are also posted on the CMS website, for entities offering MA Plans with a Part D Drug benefit at the local or regional levels, and for entities offering Cost Plans with a Part D benefit. Solicitations for PDP and MA-PD products for employer groups will be released later in 2005, as will a solicitation for Fallback Plans for potential Fallback regions, if any. A separate Part D solicitation for PACE organizations will be released later in 2005. PDP applicants or subcontractors acting as an integral part of the drug benefit management activities for the PDP may not apply to offer a Fallback Plan.

Part D Sponsors will have flexibility in terms of benefit design. This flexibility includes, but is not limited to, authority to establish a formulary that designates specific drugs that will be available within each therapeutic class of drugs, and the ability to have a cost-sharing structure other than the statutorily defined structure (subject to certain actuarial tests). (Plans would still be required to follow our formulary guidance. See Section 2.9.1 of this application). The plans also may include supplemental benefits coverage such that the total value of the coverage exceeds the value of basic prescription drug coverage.

1.4 Schedule

APPLICATION REVIEW PROCESS	
Date	**Milestone**
January 19, 2005	Registration Closes for Pre-Application Conferences in Baltimore
January 21, 2005	Posting of Part D solicitations on CMS website
January 21, 2005	Registration Closes for Pre-Application Conferences in San Diego and New Orleans
January 24 – 27, 2005	Pre-Application Conference – Baltimore
January 31 – February 1 2005	Pre-Application Conference – San Diego
February 3 – 4, 2005	Pre-Application Conference – New Orleans
February 18, 2005	1. Submit notice of intent to apply to CMS 2. Request HPMS Access (Includes User ID and Password Request)

	3. Request CMS Connectivity
March 23, 2005	Applications due
May/June 2005	CMS sends Part D contract eligibility determination to Applicants, based on review of application. Applicant's bids must still be negotiated (see below)

FORMULARY BID AND CONTRACTING PROCESS	
Date	**Milestone**
April 4 -5, 2005	CMS conducts Bid and Formulary Training Conference in Washington D.C.
March 28 - April 18, 2005	Applicants submit formularies to CMS for review
April 8, 2005	Applicants receive instructions to download Plan Benefit Package and Pricing Tool software from the Health Plan Management System (HPMS).
May 16, 2005	CMS provides preliminary approval of formularies
May 20, 2005	CMS begins accepting bid submissions via HPMS
June 6, 2005	Qualified Applicants submit bids to CMS via HPMS for each of the Part D plans they propose to offer during 2006. Disapproved applicants requesting a reconsideration of CMS' determination must submit their bids on this date as well.
June 6 - July 25, 2005	Modifications to bids accepted only at the discretion of CMS
Late July 2005	Training on submission of drug claims data to CMS
July 15, 2005	Any favorable redetermination, including those resulting from a hearing or Administrator review must be made for the contract in question to be effective on January 1 of the following year.
Early August 2005	CMS publishes national average Part D premium
September 2, 2005	CMS completes review and approval of bid data. CMS executes PDP sponsor contracts with qualified applicants who submit an acceptable bid.

PRE-IMPLEMENTATION AND IMPLEMENTATION PROCESS	
Date	**Milestone**
January 2005	Begin weekly Applicant/Sponsor technical support calls with CMS
March 23, 2005	Submit contact information and other related information to HPMS
March 28, 2005	CMS plans to release the formulary upload functionality
April 2005	Marketing guidelines posted on CMS website
April/May 2005	Reporting requirements posted on CMS website in April except data requirements for price compare will be available in May
April 2005	Enrollment requirements posted on CMS website
April 8, 2005	CMS plans to release the HPMS bid creation functionality, including the PBP and BPT software
April 18, 2005	Formularies are due to CMS

April 18, 2005	Responses to Quality Assurance and Patient Safety and Medication Therapy Management Program questions are due to CMS
April 20, 2005	Details regarding submitting pricing and pharmacy network information to be posted on www.cms.hhs.gov by this date
May 20, 2005	CMS plans to release the PBP and BPT upload functionality
May 20 – June 6, 2005	Applicants can submit bid uploads to HPMS
Early Summer 2005	Establish Connectivity AT&T Medicare Data Network (MDCN)
June 7, 2005	PDP sponsors submit electronic test data to CMS
July 2005	CMS releases Coordination of Benefits requirements
Summer 2005	Submit Banking Information Form (Appendix III)
Summer 2005	Begin testing between PDP sponsors and CMS on information systems interfaces and data exchanges
July 29, 2005	PDP sponsors submit corrected test data electronically to CMS
August 2005	Re-evaluation of pharmacy access requirements
September 2005	Training on Certification Enrollment and Payment Form Submit *Certification of Monthly Enrollment and Payment Data Relating to CMS Payment* (Appendix IX)
September 16, 2005	PDP sponsors submit actual data to CMS electronically for final testing
October 6, 2005	PDP sponsors submit data that will be published on www.medicare.gov
November 15, 2005	Part D initial enrollment period begins for individuals who are first eligible to enroll in a Part D plan on or prior to January 31, 2006
January 1, 2006	Medicare beneficiaries begin receiving drug benefits from Medicare Part D contractors
January 1, 2006	Auto-enrollment effective for beneficiaries who are full-benefit dual eligible as of December 31, 2005
May 15, 2006	Initial enrollment period ends for individuals who are first eligible to enroll in a Part D plan on or prior to January 31, 2006

NOTE: CMS reserves the right to amend or cancel this solicitation at any time. CMS also reserves the right to revise the Medicare Prescription Drug Benefit program implementation schedule, including the solicitation and bidding process timelines.

1.5 Summary of PDP Sponsor Role and Responsibilities

Key aspects of each PDP shall include the ability to:

- Submit a formulary each year for CMS approval.
- Submit a PDP plan bid each year for CMS approval.
- Enroll all eligible Medicare beneficiaries who apply and reside within the PDP's approved service area. A sponsor must serve at least one entire region.

- Administer the Part D benefit, including providing coverage for drugs included in a CMS-approved formulary, administering appropriate deductibles and co-payments, managing the benefit using appropriate pharmacy benefit managerial tools, and operating effective oversight of that benefit.

- Provide access to negotiated prices on covered Part D drugs, with different strengths and doses available for those drugs, including a broad selection of generic drugs.

- Ensure that records are maintained in accordance with CMS rules and regulations and that both records and facilities are available for CMS inspection and audit.

- Disclose the information necessary for CMS to oversee the program and ensure appropriate payments.

- Offer a contracted retail pharmacy network, providing convenient access to retail pharmacies.

- Process claims at the point of sale.

- Operate quality assurance, drug utilization review, and medication therapy management programs.

- Administer a coverage determinations, grievances, exceptions, and appeals process consistent with CMS requirements.

- Provide customer service to beneficiaries, including enrollment assistance, toll-free telephone customer service help, and education about the Part D benefit.

- Protect the privacy of beneficiaries and beneficiary-specific health information.

- Develop marketing materials and conduct outreach activities consistent with CMS standards for completeness, appropriateness, and understandability.

- Develop and/or maintain systems to support enrollment, provide claims-based data to CMS, accept CMS payment (including subsidies for low-income beneficiaries), track true out-of-pocket costs, coordinate benefits with secondary insurers (or primary insurers when Medicare is secondary) and support e-prescribing.

- Provide necessary data to CMS to support payment, oversight, and quality improvement activities and otherwise cooperate with CMS oversight responsibilities.

1.6 Summary of CMS Role and Responsibilities

Application Approval, Part D Bid Review, and Contracting Processes
There are three distinct phases to the overall review to determine whether CMS will enter into a contract with an Applicant. The first phase is the application review process. CMS will review all applications submitted on or by March 23, 2005 to determine whether the Applicant meets the qualifications we have established to enter into a Part D contract.

The second phase has two steps – the formulary review which begins April 18, 2005 and the bid review which begins June 6, 2005. The formulary review entails determining that the proposed formulary (if one is used) has at least two drugs in every therapeutic category and class (unless special circumstances exist that would allow only one drug); does not substantially discourage enrollment by certain types of Part D eligible individuals; includes adequate coverage of the types of drugs most commonly needed by Part D enrollees; and includes an appropriate transition policy. CMS will contact Applicants if any issues are identified during the review for discussion and resolution. The intent is to provide an opportunity for Applicants to make any necessary corrections prior to Part D bid submission on June 6, 2005. The second step involves the bid review and negotiations with plans to assure valuation of the proposed benefits are reasonable and actuarially equivalent.

The third phase involves contracting. Applicants judged qualified to enter into a Part D contract as a result of successfully completing phase one and two will be offered a Part D contract by CMS.

Part D Program Oversight
CMS will develop a Medicare Prescription Drug Benefit program monitoring system to ensure that the plans deliver good value through defined benefits and are compliant with program requirements. We will focus on several operational areas critical to the value of the benefit, including beneficiary access to and satisfaction with their Part D benefit and protection of the financial integrity of the program. Specific areas will include pharmacy access, adequacy and value of the benefit, benefit management, enrollment and disenrollment, marketing, program safeguard activities, customer service, confidentiality and security of enrollee information, and effectiveness of tracking true out-of-pocket expenses. The types of the reporting that CMS will require of Part D sponsors is presented in the application. Further detail on our approach to monitoring and oversight, including the exact reporting measures will be posted on the CMS website no later than April 2005. (*NOTE: PDP sponsors, as covered entities under the Privacy Rule, are subject to investigation and penalties for findings of Privacy Rule violations as determined by the Department of Health and Human Services Office for Civil Rights and the Department of Justice.)* We will monitor, through the analysis of data we collect from Part D sponsors, CMS contractors, and our own systems. The types of data we expect to collect from sponsors include: certain benefit data, claims data, cost data, benefit management data, marketing review information, and customer satisfaction and complaints data.

To monitor plan performance in the areas we have identified, we will: 1) conduct beneficiary satisfaction surveys and operate a complaints tracking system to monitor and

manage complaints brought to our attention that are not satisfactorily resolved through PDP sponsors' grievance processes; and 2) conduct periodic site visits to verify PDP sponsor compliance with Part D program requirements. We will use information from all the specified sources to analyze the appropriateness and value of the benefit delivered, and to evaluate the opportunity for additional value and quality improvement. If any trends we identify indicate less than satisfactory performance, significant departures from the marketed Part D offering, or fraud or other violations of State or Federal laws, appropriate action will be taken ranging from request for corrective action plans to all categories of sanctions consistent with 42 CFR 423.509 and Part 423, Subpart O. We also will make referrals if appropriate to the Services Office of the Inspector General, or to Federal and State authorities where violations of laws under the jurisdictions of these agencies are in question.

Education and Outreach

CMS is committed to educating Medicare beneficiaries about the Part D program. CMS plans to educate beneficiary and consumer groups, health care providers, States, and other interested groups about the Part D program. Among the topics to be discussed with these groups is the identification and reporting of possible fraud and/or abuse. CMS may also engage in other activities that publicize or otherwise educate beneficiaries about the program.

Marketing Guidelines and Review

CMS is developing marketing guidelines and expects to post them on the CMS website as a separate document from this solicitation no later than April 2005. Part D sponsors are required to adhere to these guidelines in developing their marketing materials and marketing strategy. We will retain a contractor to provide technical assistance in the development of these guidelines and review materials submitted by plans in accordance with statutory requirements. PDP sponsors are required to submit materials to CMS based on the marketing guidelines.

Eligibility for the Low Income Subsidy Program

Low-income Medicare beneficiaries will receive full or partial subsidies of premiums and reductions in cost sharing under the Part D benefit. Certain groups of Medicare beneficiaries will automatically be eligible for the low-income subsidy program. These beneficiaries include full-benefit dual eligible individuals, Medicare beneficiaries who are recipients of Supplemental Security Income benefits, and participants in Medicare Savings Programs as Qualified Medicare Beneficiaries (QMBs), Specific Low-Income Medicare Beneficiaries (SLMBs), and Qualifying Individuals (QIs). Beneficiaries who are low-income and who do not fall into one of the automatic subsidy eligibility groups will apply for a low-income subsidy and have their eligibility determined by either the states in which they reside or the Social Security Administration (SSA). We will develop a database to track individuals who are automatically deemed subsidy-eligible or who are determined subsidy-eligible by states or SSA, and communicate the names and eligibility category of those individuals to plan sponsors as part of the enrollment files from the enrollment processing system described below.

General Enrollment Processing

CMS has developed a system to review an individual's eligibility for the Part D benefit. For individuals applying for enrollment in a Part D plan, CMS will review an individual's status as a Medicare beneficiary. CMS will track enrollments and ensure enrollment exclusivity. CMS will also track low-income subsidy status and auto-enrollments of full-benefit dual eligible individuals into Part D plans. Finally, CMS will track dis-enrollments from Part D plans and will deny new enrollments during any given year unless the enrollment occurs during an allowable enrollment period.

Payment to PDPs

CMS will provide payment to PDP sponsors in the form of advance monthly payments (consisting of the PDP plan's standardized bid, risk adjusted for health status, minus the beneficiary monthly premium), estimated reinsurance subsidies, and estimated low-income subsidies. After the end of the payment year, CMS will reconcile the correct amounts of low-income subsidies and reinsurance amounts against the amount paid as a part of the prospective monthly payments. Risk sharing amounts (if applicable) will be determined after all other reconciliations have been completed. For a more complete description refer to *Prescription Drug Event Data* at www.cms.hhs.gov/pdps/PrescriptionDrugEventDataPaper.pdf.

2. INSTRUCTIONS

2.1 Overview

There are three types of entities with which CMS will contract to operate Medicare prescription drug benefit plans: PDPs, MA-PDs, and Fallback Plans. This application is to be completed by those entities seeking contracts as PDPs (unless the PDP is for an employer group). (Although the regulation includes fallbacks in the definition of a PDP sponsor, in these applications we use PDP to refer to the at-risk contractors, and fallback to refer to the non-at-risk contractors).

2.2 Pre-Application Conferences

CMS will conduct three conferences for potential Medicare Advantage (MA) and Prescription Drug Plan (PDP) sponsors to learn about requirements for plans under the MMA. The following conferences are planned:

- January 24-27, 2005 in Baltimore , Maryland
- January 31-February 1, 2005 in San Diego , California ; and
- February 3-4, 2005 in New Orleans, Louisiana

The Baltimore conference is a four-day technical assistance and guidance conference for the Medicare Advantage and Prescription Drug industries on the new opportunities available under the Medicare Prescription Drug, Improvement, and Modernization Act. The conference will be conducted January 24-27, 2005 at the Radisson Lord Baltimore Hotel, Baltimore, Maryland. The conference will include sessions on the prescription drug plan and Medicare Advantage applications processes, regional PPOs, and employer group options. The training for potential drug benefit sponsors will be focused on completing the application. CMS strongly encourages the new and transitioning PACE programs, along with those with demonstration projects to attend the Baltimore conference. Information regarding registration, accommodations and other details for this conference can be accessed at http://cms.c2ti.com/industry. Registration closes for this conference on January 19, 2005.

In addition, conferences have also been scheduled for January 31-February 1 in San Diego and for February 3-4 in New Orleans for the convenience of PDP and MA representatives who are unable to attend the January 24-27, 2005 Industry Conference in Baltimore. These two conferences will have very similar content to the Baltimore conference but will be conducted with simultaneous PDP and MA sessions. Consequently, organizations that wish to hear about both MA and PDP at these conferences should plan to send two staff to cover both sessions. Information regarding registration, accommodations and other details for the San Diego and New Orleans conferences can be accessed at www.aspenxnet.com\partd. Registration closes for these two conferences on January 21, 2005.

Please note that the San Diego and New Orleans conferences will cover the same PDP topics presented in Baltimore; however, the field conferences will not cover some MA topics such as appeal rules that are largely unchanged by the Medicare Modernization Act, but may nonetheless be of interest to potential new MA contractors. These topics will be covered in the Baltimore conference only. Therefore, CMS strongly encourages new MA organizations to attend the Baltimore conference.

2.3 Other Technical Support

CMS will conduct weekly technical support calls for Applicants from January 19, 2005 through June 2005, followed by bi-weekly calls. CMS operational experts (e.g. enrollment, information systems, marketing, bidding, formulary design, and coordination of benefits) will be available to discuss and answer questions on the agenda items for each meeting. Registration for the technical support calls can be found at www.aspenxnet.com/partd/usergroups.

2.4 Notice of Intent to Apply

To assist CMS in planning for the review of applications and to ensure that potential Applicants are notified of any additional guidance posted on the web, and for future correspondence, potential PDP Applicants should notify CMS of their intention to apply by 5:00 p.m. EST on **February 18, 2005**. Organizations that submit notices of intent to apply are not obligated to submit an application to CMS. However, CMS will not consider, under this solicitation process, an application for approval from an entity that has not submitted a timely "*notice of intent to apply*".

All PDPs are required to submit a notice of intent to apply to offer the Part D drug benefit. Employer group applicants that intend to offer an employer-sponsored PDP should NOT submit a notice of intent at this time. A separate solicitation process for these employer-based products will be made available later in the year. PDP Applicants seeking approval to offer multiple Part D plans should submit only one notice of intent to apply.

There are three steps to submit a Notice of Intent to Apply:

Step 1	Complete *Notice of Intent Form* (Appendix VIII) and Email to CMS	Applicants must send a notice of its intent to apply by email to drugbenefitimpl@cms.hhs.gov with "NOTICE OF INTENT" indicated in the subject field.
Step 2	Complete *CMS Connectivity Request Form* (Appendix I) and Email to CMS	As part of the notice of intent submission, Applicant must also complete the *CMS Connectivity Request* form, which is necessary to conduct enrollment transactions. Complete and submit it at the same time as the notice of intent to apply to the email address: mdcn@cms.hhs.gov . Questions about this form may also be directed to the same e-mail resource.

Step 3	Complete *Application for Access to CMS Computer Systems* (located on CMS website) and Mail to CMS	Applicant must also submit the *Application for Access to CMS Computer Systems* form (found on the CMS website www.cms.hhs.gov/mdcn/access.pdf). Please see *Accessing CMS Systems* (Appendix II) for instructions on completing the *Application for Access to CMS Computer Systems* form. Document should be mailed as a hard-copy with original signature to: Centers for Medicare & Medicaid Services Attention: Marietta Mack Mail Stop S1-05-06/Location S2-04-05 7500 Security Boulevard Baltimore, Maryland 21244-1850

2.5 Health Plan Management System (HPMS) Data Entry

PDP organizations that submit a notice of intent to apply will be assigned a pending contract number (S number) to use throughout the application and subsequent operational processes. Once the contract number is assigned, PDP Applicants will receive their CMS User ID(s) and password(s) for HPMS access and will need to input contact and other related information into the Health Plan Management System (HPMS). Applicants will be required to provide prompt entry and ongoing maintenance of these data in HPMS, which will facilitate the tracking of your application throughout the review process.

In the event that an Applicant is awarded a contract, this information will also be used for frequent communications during implementation. Therefore, it is important that this information be accurate at all times.

The HPMS data being requested includes, but may not be limited to the following:

Provide the trade name for your organization, if different than the legal entity name
Website address for applicant's organization
Provide information for the individuals in your organization who would be the primary contact for the service/position listed below. Include Name, Mailing Address, Phone Number, Fax, and Email for each of the following: • Bid Pricing • CEO • CFO • Call Center • Claims Submission • Enrollment System • HIPAA Security Officer • HIPAA Privacy Officer • Marketing • Medicare Compliance Officer • Medicare Payment System • Medication Therapy Management • Network Management • Patient Safety

• Part D Benefits • Pharmacy Benefit Management (from applicant's organization) • Quality Assurance • Utilization Management
Provide information on members of your organization's P&T Committee: • Full Name of Members • Practice/Expertise (Physician, Pharmacist) • Expertise with Elderly or Disabled? • Is member free of conflict of interest with: - Part D sponsor? - Part D plan? - Pharmaceutical manufacturers?

CMS will provide further guidance to PDP Applicants upon submission of the notice of intent to apply concerning the final data elements to be entered into HPMS in support of the application process.

2.6 Instructions and Format of Qualifications

Instructions

In preparing your application in response to the prompts in Section 3.0 of this solicitation, please mark "Yes" or "No" in sections organized with that format.

In many instances Applicants are directed to affirm that they will meet particular requirements by indicating "Yes" next to a statement of a particular Part D program requirement. By providing such attestation, an Applicant is committing its organization to complying with the relevant requirements as of September 15, 2005, unless an alternative date is noted in Section 3.0.

Additional supporting documentation is notated in the following manner throughout the application and is to be submitted as follows:

1. Appendices: documents supplied by CMS that are contained at the end of this application. They are to be completed by the Applicant and returned to CMS as indicated.

2. Attachments – documents that are to be created and/or supplied by the Applicant and sent to CMS with the application. Attachments are to be used only when the application does not indicate to respond directly below the question. (i.e. Pharmacy Lists, subcontracts, etc.)

More specifically, Pharmacy Lists requested in Section 3.4, should only be submitted electronically on a Computer Diskette (CD) using Microsoft Excel (*see Format section below for instructions on creating the CDs and Section 3.4 for specific information on creating the pharmacy lists).* Due to the amount of data - hard copies of these lists should not be included with the application.

Legal documents such as subcontracts should be provided in hard copy as an attachment to the application. They should also be provided on the CD associated with the relevant application section. The CD identification should include the appendix number.

CMS will check the application for completeness shortly after its receipt. We will notify Applicants of any deficiencies and afford them the opportunity to amend their applications.

While PDP sponsors are not required to begin providing the Part D benefit until January 1, 2006, CMS has established the September 15, 2005 compliance deadline to allow adequate time for sponsors to cure any operational deficiencies before beneficiaries become entitled to Part D services. As with all aspects of a PDP sponsor's operations under its contract with CMS, we may verify a sponsor's compliance with qualifications it attests it will meet, through on-site visits at the PDP sponsor's facilities as well as through other program monitoring techniques. Failure to meet the requirements attested to in the Applicant's response to this solicitation and failure to operate its Part D plan(s) consistent with the requirements of the applicable statutes, regulations, and the Part D contract may delay a PDP sponsor's marketing and enrollment activities or, if corrections cannot be made timely, disqualify it from participation in the Part D program.

An individual with legal authority to bind the Applicant shall sign and submit the certification found in Section 4.0. CMS reserves the right to request clarifications or corrections to a submitted application. Failure to provide requested clarifications within a 2-day period could result in the applicant receiving an intent to deny the application, in which case, the Applicant will then have 10 days to seek to remedy its application.

This solicitation does not commit CMS to pay any cost for the preparation and submission of an application.

Format

- To assure that each CMS review panelist receives the application in the manner intended by the applicant, Applicants should deliver a total of four (4) hard copies of the written application and supporting documentation.

- All hard copies should be in separate 3-ring binders. Tab indexing should be used to identify all of the major sections of the application. Page size should be 8 ½ by 11 inches and the pages should be numbered. Font size should be 12 point.

- One application should be clearly marked, "Original" and contain all original signed certifications requested in the application.

- Additionally, the Applicant must submit the written application and supporting documentation electronically using (CDs). This will support the review of the application by different CMS components. The Applicant must submit 4 sets of the 5 CDs identified below. Each set should be inserted inside of each hard copy application being submitted.

CD NUMBER	CONTENTS ON CD
CD #1	Entire Application and Supporting Documentation – including Appendices, and Attachments (*Do Not Include Pharmacy Lists*)
CD #2	Subsection 3.1.1 and Subsection 3.1.2 and related Appendices and Attachments
CD #3	Subsection 3.1.3 and related Appendices and Attachments
CD #4	Subsections 3.1.4 and Section 3.12 and related Appendices and Attachments
CD #5	Section 3.3 and Section 3.4 and related Appendices and Attachments (includes Pharmacy Lists)

- All responses should be completed in Microsoft Word (in a version that is compatible with Office 2003). Attachments (such as existing contracts) can be submitted in Microsoft Word (in a version that is compatible with Windows 2003) or as a PDF file. Pharmacy lists should be created in Microsoft Excel (in a version that is compatible with Office 2003).

- Each CD must be clearly labeled with the information in the table below:

Applicant's Organization Name
CMS Identification Number
CD Number (as notated above)
Section and/or Subsection Number and Name

- Failure to submit an application consistent with these instructions may delay its review by CMS and could result in receipt of an intent to deny.

- Applications must be sent to:

Centers for Medicare & Medicaid Services (CMS)
Marietta Mack
Multi-Purpose Room
Attn: Part D Application
7500 Security Boulevard
Baltimore, Maryland 21244-1850

- Applications mailed through carriers that do not have CMS Security Clearance could be delayed due to clearance processing. Carriers with CMS Security Clearance include Federal Express and Airborne Express.

- CMS will not review applications received after 5:00 P.M. EST on March 23, 2005.

Single Application Representing Multiple Plans

Part D Plans of the same type, offered by the same legal entity, regardless of their service area may be represented in a single application. There are three types of Part D solicitations for which applications are due on March 23, 2005; they are PDP, MA-PD, and Cost Plan solicitations. Entities that intend to offer a combination of these types of Part D plans must submit a separate application for each type. (Employer and PACE plan sponsors will also have separate solicitations.) For example, an MA-PD and PDP product may not be represented in the same application. Also, entities intending to offer both local MA-PD and Regional PPO plans must submit separate MA-PD applications. If an Applicant's response to any inquiry in the application is different for one plan than another, this delineation must be clearly identified at the beginning of each section of the application where such delineation is made. The Applicant must use consistent nomenclature to distinguish between the plans as necessary throughout the application. The Applicant must submit a face sheet to the application indicating that multiple plans are represented in the application, whether plan-specific delineations are made, the nomenclature to distinguish among the plans, and in what sections and subsections of the application.

Applicant Entity Same as Contracting Entity

The legal entity that submits this application must be the same entity with which CMS enters into a Part D contract, or in the case of an MA-PD and Cost Plan sponsor, the same legal entity seeking an addendum to an MA or Cost Plan contract. An entity that qualifies for a Part D contract, or for an addendum to an MA or Cost Plan contract, may offer multiple plans of the same type (e.g. PDP, MA-PD, or Cost Plan) in the service area described in the application.

Joint Enterprise as Applicant and Contracting Entity

CMS will recognize as Applicants those joint enterprises formed by agreement among multiple state-licensed organizations (or organizations that have applied to CMS for a licensure waiver) for the purpose of administering a Medicare Prescription Drug Plan in at least one entire PDP region. Each member of the joint enterprise will be contractually liable to CMS for the administration of the Part D benefit in the State(s) in which it is licensed or for which it has received a CMS licensure waiver.

The joint enterprise need submit only one application on behalf of the enterprise's member organizations and such application shall represent a uniform benefit. However, the information requested in Section 3.1 of this solicitation must be provided for each member of the joint enterprise with separate accompanying Appendices as necessary. For example, each joint enterprise member must provide identifying information about its organization, copies of its executed contracts with entities performing critical tasks related to the delivery of the Part D benefit, and information related to its business integrity. The responses provided in the remainder of the application may be made once by the joint enterprise applicant and will be considered binding on each member of the joint enterprise. Also, a separate certification statement, shown in Section 4.0, must be provided for each joint enterprise member organization. Each certification statement

must be signed by an individual specifically granted the authority to bind the member organization.

Joint enterprise applicants are required to submit to CMS for approval a copy of the executed agreement among the joint enterprise member organizations. Please see Section 3.1.1.I for instructions concerning this requirement.

Upon CMS's determination that the members of the joint enterprise are qualified to enter into a Part D contract and approval of the bid(s) submitted by the joint enterprise, CMS will enter into a multiple-party contract signed by authorized representatives of CMS and each member of the joint enterprise.

2.7 Submission Software Training

Applicants will use the CMS Health Plan Management System (HPMS) during the application, formulary, and bid processes. Applicants will be required to enter contact and other information collected in HPMS in order to facilitate the application review process.

Applicants will be required to upload their plan formularies to HPMS using a pre-defined file format and record layout. CMS plans to release the formulary upload functionality on March 28, 2005. Formularies are due to CMS on April 18, 2005.

In order to prepare plan bids, Applicants will use HPMS to define their plan structures and associated plan service areas and then download the Plan Benefit Package (PBP) and Bid Pricing Tool (BPT) software. For each plan being offered, Applicants will use the PBP software to describe the detailed structure of their Part D benefit and the BPT software to define their bid pricing information. The formulary must accurately crosswalk to the PBP. The combination of the PBP and BPT for a plan comprises a bid. CMS anticipates releasing the HPMS bid creation functionality, including the PBP and BPT software, on April 8, 2005.

Once the PBP and BPT software has been completed for each plan being offered, Applicants will upload their bids to HPMS. CMS anticipates releasing the PBP and BPT bid upload functionality on May 20, 2005. Applicants will be able to submit bid uploads to HPMS on their PBP or BPT one or more times between May 20, 2005 and the CY 2006 bid deadline of June 6, 2005. CMS will use the last successful upload received for a plan as the official bid submission.

CMS will provide technical instructions and guidance upon release of the HPMS formulary and bid functionality as well as the PBP and BPT software. In addition, systems training will be available at the Bid Training in April 2005.

2.8 System and Data Testing with CMS

HPMS

PDP organizations will use HPMS to communicate with CMS in support of the application process, formulary submission process, bid submission process, ongoing operations of the Part D program, and reporting and oversight activities. PDP sponsors are required to secure access to HPMS in order to carry out these functions.

Applicants should reference *Accessing CMS Systems* (Appendix II) for instructions on establishing access to HPMS. CMS asks that Applicants submit their HPMS User Access Request Forms at the time of submission of the notice of intent to apply. Establishing connectivity will ensure that Applicants have sufficient time to prepare and submit their formularies to HPMS by April 18, 2005 and their PBPs and BPTs by June 6, 2005.

Enrollment

PDP sponsors will be required to establish connectivity to CMS via the AT&T Medicare Data Communications Network (MDCN). This secure network allows direct transmission of enrollment information to CMS for processing.

- CMS recommends that PDP sponsors contact AT&T to establish connectivity 3 months prior to beginning file transmissions.
- AT&T can be contacted on 1-800-905-2069.
- PDP sponsors must also obtain a CMS User ID and password.
- Download the User Access Form located at www.cms.hhs.gov/mdcn/access.pdf, complete it and mail it to your assigned CMS plan manager.

CMS will communicate a beneficiary's eligibility for enrollment in a Part D plan as well as for a low-income subsidy. CMS will also determine whether a beneficiary must pay a late enrollment penalty. CMS will record the results of this processing and reply to the PDP. Monthly membership listings will be made available for reconciliation purposes. They will be downloaded using the MDCN connectivity. Similarly, PDP sponsors will be required to report disenrollment information to CMS.

A test environment will be established to accept, process, and reply to PDP transmissions. In addition, Help Desk staff will be available to assist PDP sponsors in this process and to trouble-shoot reported problems. Testing is expected to occur during the summer of 2005. Specific instructions will be provided prior to that time.

Payment – PDP Sponsors

Payments will be wired to sponsor accounts on the first business day of each month (or the last business day of the prior month if the first day of the month is not a business day). PDPs that enter into a contract with CMS must submit the *Banking Information Form* (Appendix III) so that payments can be transmitted to your account.

The monthly payment will include premiums that SSA or other agencies are deducting from beneficiary Social Security payments as well as those premiums CMS is paying on behalf of low-income individuals. Estimated monthly reinsurance subsidies, and low-income subsidies will also be included.

Monthly beneficiary-level payment reports will be available detailing the components of each payment for reconciliation purposes. PDP-level reports summarizing the monthly payment and any applicable adjustments will also be provided. PDPs will download these reports via their MDCN connectivity.

Test versions of these reports will be provided in late summer of 2005. Specific testing instructions will be provided at a later date.

2.9 Summary Instruction and Format for Bids

Each PDP and MA-PD Applicant must submit to CMS a bid for each prescription drug plan it intends to offer. Applicants using this solicitation may apply to offer full or limited risk plans. CMS will review bids for limited risk plans only in those regions where there are not at least two prescription drug plans, one of them being a PDP plan. Note, that only PDP sponsor Applicants and not MA organizations may submit a bid to be limited risk. Furthermore, in the event a PDP region does not have two prescription drug plans, CMS will approve at a maximum two partial risk plans. (Please note that Applicants that indicate in their applications that they intend to offer limited risk plans are not precluded from later submitting full risk bids, but a PDP sponsor Applicant that does submit a limited risk bid must apply the same limitation of risk to all PDPs offered by sponsor in the PDP region). Where there are not at least two plans offering qualified prescription drug coverage, one of them being a PDP plan, CMS will contract with entities to offer fallback plans. Applicants must submit their formularies to HPMS on or before April 18, 2005 and the PBPs and BPTs on or before June 6, 2005.

2.9.1 Format of Bids

Bid Submission Sections Due Prior to June 6, 2005

To facilitate the timely review of all the bid submissions, CMS expects to require Applicants to submit the portion of their bid related to formulary and covered drugs by April 18, 2005. CMS will review areas of each proposed drug plan formulary by tier and drug availability and evaluate each element against evidence-based standards such as widely accepted treatment guidelines. Elements will include, but may not be limited to the list of drugs, the categories and classes, tier structures (not cost sharing), and utilization management tools such as quantity limits, step therapy, and prior authorization. CMS will make the review criteria available to Applicants well in advance of the date Applicants must submit this information to CMS. Outliers will be selected for further review of the formulary development process prior to CMS approval of the bid. CMS will make reasonable efforts to inform Applicants of their

outliers so that they may substantiate their offering. If such substantiation is not satisfactory to CMS, the Applicant will be given the opportunity to modify the formulary. CMS intends to complete as much of this work as possible before the June 6, 2005, PBP and BPT submissions so that any modification may be reflected in those documents.

Bid Submission Due June 6, 2005

The Applicant's bid will represent the expected monthly cost to be incurred by the Applicant for qualified prescription drug coverage in the approved service area for a Part D-eligible beneficiary on a standardized basis. The costs represented in each bid should be those for which the Applicant would be responsible. These costs would not include payments made by the plan enrollee for deductible, coinsurance, co-payments, or payments for the difference between the plan's allowance and an out-of-network pharmacy's usual and customary charge. The bid will require the separate identification, calculation, and reporting of costs assumed to be reimbursed by CMS through reinsurance. CMS requires that the bid represent a uniform benefit package based upon a uniform level of premium and cost sharing among all beneficiaries enrolled in the plan. The benefit packages submitted must be cross walked appropriately from the formulary. Pursuant to 423.505(k)(4), the CEO, CFO, or a delegee with the authority to sign on behalf of one of these officers, and who reports directly to such officer, must certify (based on best knowledge, information and belief) that the information in the bid submission, and assumptions related to projected reinsurance and low-income cost sharing subsidies, is accurate, complete, and truthful, and fully conforms to the requirements in section 423.265 of the regulations. In addition, the pricing component of the bid must also be certified by a qualified actuary.

2.9.2 CMS Review of Bids

CMS will evaluate the bids based on four broad areas: 1) administrative costs, 2) aggregate costs, 3) benefit structure, and 4) plan management. CMS will evaluate the administrative costs for reasonableness in comparison to other bidders. CMS will also examine aggregate costs to determine whether the revenue requirements for qualified prescription drug coverage are reasonable and equitable. In addition, CMS will review the steps the PDP sponsor is taking to control costs, such as through various programs to encourage use of generic drugs. Finally, CMS will examine indicators concerning plan management, such as customer service.

CMS is also required to make certain that bids and plan designs meet statutory and regulatory requirements. We will conduct an actuarial analysis to determine whether the proposed benefit meets the standard of providing qualified prescription drug coverage. Also, CMS will review the structure of the premiums, deductibles, co-payments, and coinsurance charged to beneficiaries and other features of the benefit plan design to ensure that it is not discriminatory (that is, that it does not substantially discourage enrollment by certain Part D eligible individuals).

2.9.3 Overview of Bid Negotiation

CMS expects to evaluate the reasonableness of bids submitted by PDP sponsors by means of an actuarial valuation analysis. This requires evaluating assumptions regarding the expected distribution of costs, including average utilization and cost by drug coverage tier. CMS could test these assumptions for reasonableness through actuarial analysis and comparison to industry standards and other comparable bids. Bid negotiation could take the form of negotiating changes upward or downward in the utilization and cost per script assumptions underlying the bid's actuarial basis. We could exercise our authority to deny a bid if we do not believe that the bid and its underlying drug prices reflect market rates.

2.10 Standard Contract with PDP Sponsors

Successful Applicants will be deemed qualified to enter into a Part D contract with CMS to operate one or more Medicare prescription drug plans. Only after the qualified Applicant and CMS have reached agreement on the Applicant's bid submissions will the Applicant be asked to execute its Part D contract.

The Part D contract will be for an initial 16-month term (September 1, 2005 through December 31, 2006), renewable after the initial term for one-year periods at the end of each calendar year at the option of both CMS and the Applicant. The initial 16-month contract period is intended to ensure that PDP sponsors meet enrollment and marketing requirements prior to the January 1, 2006 start date of the first Part D benefit period. CMS expects to provide a draft of the contract in Spring 2005.

2.11 Additional Information Available

To assist Applicants in preparing the retail pharmacy network access analysis, CMS has posted a data file at http://www.cms.hhs.gov/pdps/ that contains total Medicare beneficiary counts by ZIP code. This file also include markers for MA and PDP regions. The file name is "MCareEnrbyZip062004.zip."

To assist Applicants in preparing their long-term care (LTC) pharmacy access analysis, CMS has provided Applicants with a data file at http://www.cms.hhs.gov/pdps/ that contains information on LTC facility location (address, state, zip code, MA region, and PDP region) and certified bed count. The file name is "LTCFacilities012005.zip."

To assist Applicants in preparing their bids, CMS has made the following drug use and drug spending information available at http://www.cms.hhs.gov/pdps/ :

- Individual-level data from the Medicare Current Beneficiary Survey (MCBS)
- Continuance tables based on MCBS data
- Medicaid data based on 48 states
- State-level expenditure adjusters based on Federal retirees in a national plan; Medicaid drug expenditure data for most states
- Drug costs imputed from the MCBS to a 5 percent sample of Medicare beneficiaries

2.12 Protection of Confidential Information

Applicants can always seek to protect their information under the Freedom of Information Act and label truly proprietary information "confidential" or "proprietary." When information is so labeled, the Applicant is required to explain the applicability of the FOIA exemption they are claiming. When there is a request for information that is designated by the Applicant as confidential or that could reasonably be considered exempt under Exemption 4, CMS is required by its FOIA regulation at 45 C.F.R. §5.65(d) and by Executive Order 12,600 to give the submitter notice before the information is disclosed. To determine whether the Applicant's information is protected by Exemption 4, the Applicant must show that— (1) disclosure of the information is likely to impair the government's ability to obtain necessary information in the future; (2) disclosure of the information is likely to cause substantial harm to the competitive position of the submitter; or (3) the records are considered valuable commodities in the marketplace which, once released through the FOIA, would result in a substantial loss of their market value. Consistent with our approach under the Medicare Advantage program, we would not release information under the Medicare Part D program that would be considered proprietary in nature.

3. APPLICATION

Note: Nothing in this application is intended to supersede the regulations at 42 CFR Part 423. Failure to reference a regulatory requirement in this application does not affect the applicability of such requirement, and PDP sponsors and/or Applicants are required to comply with all applicable requirements of the regulations in Part 423 of 42 CFR.

3.1 Applicant Experience, Contracts, Licensure and Financial Stability

SPECIAL INSTRUCTIONS FOR JOINT ENTERPRISE APPLICANTS: If an application is being submitted by a joint enterprise, as described above in Section 2.6, a separate set of responses to the requirements in Section 3.1. must be provided as part of this application by each member organization of the joint enterprise.

3.1.1 Management and Operations

A. Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:	YES	NO
1. Applicant is applying to operate as a PDP sponsor.		
2. Applicant is a non-governmental legal entity that agrees to abide by the terms of a Medicare Prescription Drug Plan contract with CMS.		
3. Applicant is not applying to operate as a Fallback entity nor are its subcontractors that play an integral part in the drug benefit management activities.		
4. Applicant has administrative and management arrangements that feature a policy-making body (e.g., board of directors) exercising oversight and control over the PDP sponsor's policies and personnel (e.g., human resources) to ensure that management actions are in the best interest of the organization and its enrollees.		
5. Applicant has administrative and management arrangements that feature personnel and systems sufficient for the PDP sponsor to organize, implement, control and evaluate financial and marketing activities, the furnishing of prescription drug services, the quality assurance, medication therapy management, and drug and drug utilization management programs, and the administrative aspects of the organization.		
6. Applicant has administrative and management arrangements that feature an executive manager whose appointment and removal are under the control of the policy-making body.		
7. Applicant has administrative and management arrangements that feature a fidelity bond or bonds, procured by the Applicant, in an amount fixed by its policymaking body, but not less than $100,000 per individual, covering each officer and employee entrusted with the handling of its funds.		
8. Applicant has administrative and management arrangements that feature insurance policies secured and maintained by the Applicant, and approved by CMS to insure the Applicant against losses arising from professional liability claims, fire, theft, fraud, embezzlement, and other casualty risks.		
9. Applicant provides evidence of and maintains contracts or other legal arrangements between or among the entities combined to meet the functions identified in subsection 3.1.2 A .		

B. Complete the form below:

IDENTIFY YOUR ORGANIZATION BY PROVIDING THE FOLLOWING INFORMATION
Full Legal Organization's Name:
Full Address of Your Organization's Headquarters *(Street, City, State, Zip):*
Name of Chief Executive Officer:
Name of Chief Operating Officer:
Name of Chief Financial Officer:
Type of Ownership: ☐ Sole Proprietorship ☐ Partnership ☐ Publicly-Traded Corporation ☐ Privately- Held Corporation ☐ Other (list type)_____
Name of Your Organization's Parent Organization, if any:
State in Which your Organization is Incorporated or Otherwise Organized to do Business:
Federal Taxpayer Identification Number:
PROVIDE NAME AND TITLE OF INDIVIDUAL WHO WILL SIGN THE MEDICARE PDP CONTRACT, IF APPLICATION AND BID ARE SUCCESSFUL. PLEASE SEE 42 CFR §423.502(b). THIS PERSON MUST BE AUTHORIZED TO ACT FOR

THE ENTITY	
Name of Individual:	Title:
PROVIDE YOUR COMPANY'S CONTACT INFORMATION FOR PERSON WHO CAN ANSWER QUESTIONS REGARDING YOUR ORGANIZATION'S PROPOSAL	
Name of Individual:	Title:
Telephone Number:	Fax Number:
Email Address:	

C. Provide below a brief summary of the history, structure and ownership of your organization. Include a chart showing the structure of ownership, subsidiaries, and business affiliations. The organizational chart should depict the placement of the Medicare PDP operations within your organization as well as the reporting structure within your organization:

D. Describe below your staffing plan for the operation of your Part D benefit plan(s). In particular, discuss the number of staff that will be assigned to the following activities:

- **Financial**
- **Marketing**
- **Furnishing of Prescription Drug Services**
- **Quality Assurance**
- **Fraud and Abuse**
- **Medication Therapy Management**
- **Drug Utilization Management**
- **Claims Processing**

E. Complete the form below(s) to identify each of the entities with which you subcontract to serve the functions identified in Subsection 3.1.2 A. If more than one subcontractor has been engaged to meet these functions, identify each of the subcontractors within the relevant requirement column. Copy and paste the form, if you need additional space:

IDENTIFY YOUR SUBCONTRACTOR BY PROVIDING THE FOLLOWING INFORMATION	
Full Legal Organization's Name of Subcontractor:	Function(s) Contracted for:
Full Address of Subcontractor's Headquarters *(Street, City, State, Zip):*	
Name of Chief Operating Officer:	
Name of Chief Financial Officer:	
Type of Ownership: ☐ Sole Proprietorship ☐ Partnership ☐ Publicly-Traded Corporation ☐ Privately- Held Corporation ☐ Other (list type)_____	
Name of Subcontractor's Parent Organization, if any:	
State in Which Your Subcontractor is Incorporated or Otherwise Organized to do Business:	
Federal Taxpayer Identification Number:	
PROVIDE INDIVIDUAL WHO WILL SIGN THE MEDICARE CONTRACT WITH PDP APPLICANT. THIS PERSON MUST BE AUTHORIZED TO ACT FOR THE SUBCONTRACTOR ENTITY:	
Name of Individual:	Title:

F. Provide as attachments (as instructed in Section 2.6) copies of executed contracts with each subcontractor identified in the above tables (3.1.1 E) that:

1. Clearly identify the parties to the contract (or letter of agreement);

2. Describe the functions to be performed by the subcontractor, as well as any reporting requirements the subcontractor has to the Applicant;

3. Contain language clearly indicating that the subcontractor has agreed to participate in your Medicare Prescription Drug Benefit program (except for a network pharmacy if the existing contract would allow participation in this program), and flow-down clauses requiring their activities be consistent and comply with the Applicant's contractual obligations as a PDP sponsor;

4. Contain language describing the services to be performed in a manner that encompasses the services required to support the Medicare Prescription Drug Benefit program;

5. Describe the payment the subcontractor will receive for performance under the contract, if applicable;

6. Are for a term of at least the first year of the program. (Please note that first year contracts between the Applicant and an entity performing Part D enrollment functions on behalf of the Applicant should have a start date no later than November 15, 2005, the first date of the first annual election period for Part D enrollments to be made effective January 1, 2006. Future year terms are January 1 to December 31.);

7. Are signed by a representative of each party with legal authority to bind the entity;

8. Contain language obligating the subcontractor to abide by all applicable Federal and State laws and regulations and CMS instructions;

9. Contain language obligating the subcontractor to abide by State and Federal privacy and security requirements, including the confidentiality and security provisions stated in the regulations for this program at 42 CFR §423.136;

10. Contain language ensuring that the subcontractor will make their books and other records available in accordance with 42 CFR 423.505 (i)(2). Generally stated these regulations give HHS, the Comptroller General, or their designees the right to inspect, evaluate and audit books and other records and that these rights continue for a period of 10 years from the final date of the contract period or the date of audit completion, whichever is later;

11. Contain language that the subcontractor will ensure that beneficiaries are not held liable for fees that are the responsibility of the PDP sponsor;

12. Contain language that if the Applicant, upon becoming a PDP sponsor, delegates an activity or responsibility to the subcontractor, that such activity or responsibility may be revoked if CMS or the PDP sponsor determines the subcontractor has not performed satisfactorily. The subcontract may include remedies in lieu of revocation to address this requirement;

13. Contain language specifying that the Applicant, upon becoming a PDP sponsor, will monitor the performance of the subcontractor on an ongoing basis; and

14. If the subcontractor will establish the pharmacy network or select pharmacies to be included in the network contain language that the PDP sponsor retains the right to approve, suspend, or terminate any arrangement with a pharmacy.

Note: While CMS is only requesting certain contracts, elements 2, 8, 10, 11, 12, and 13 of section 3.1.1 F are required in all the Applicants contracts necessary to provide the Part D benefit.

G. Provide as an attachment the signed certification in Appendix XI. The certification allows the Applicant to verify that the subcontracts submitted under 3.1.1 F meet all of the requirements identified in 3.1.1F.

H. Provide electronic lists of the subcontract citations demonstrating that the requirements of Section 3.1.1F are included in the subcontracts. Submit these data by creating a spreadsheet in Microsoft Excel that mimics Appendix XII. Provide this attachment on a CD as instructed in Section 2.6.

I. SPECIAL REQUIREMENT FOR JOINT ENTERPRISE APPLICANTS: Joint Enterprise Applicants must provide as part of their application a copy of the agreement executed by the State-licensed entities describing their rights and responsibilities to each other and to CMS in the operation of a Medicare Part D benefit plan. Such an agreement must address at least the following issues:

- Termination of participation in the joint enterprise by one or more of the member organizations; and
- Allocation of CMS payments among the member organizations.

Further guidance may also be provided regarding the terms and conditions of the joint enterprise contract.

3.1.2 Experience and Capabilities

A. Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN.	YES	NO
1. Applicant and/or one of its subcontractors currently operates a pharmacy benefit program that performs adjudication and processing of pharmacy claims at the point of sale.		
2. Applicant and/or one of its subcontractors currently operates a pharmacy benefit program that performs negotiation with prescription drug manufacturers and others for rebates, discounts, or other price concessions on prescription drugs.		
3. Applicant and/or one of its subcontractors currently operates a pharmacy benefit program that performs administration and tracking of enrollees' drug benefits in real time.		
4. Applicant and/or one of its subcontractors currently operates a pharmacy benefit program that performs coordination with other drug benefit programs, including, for example, Medicaid, state pharmaceutical assistance programs, Medigap, or other insurance.		
5. Applicant and/or one of its subcontractors currently develops and maintains a pharmacy network.		
6. Applicant and/or one of its subcontractors currently operates a pharmacy benefit program that operates an enrollee grievance and appeals process.		
7. Applicant and/or one of its subcontractors currently operates a pharmacy benefit program that performs customer service functionality, that includes serving seniors and persons with a disability.		

B. As part of the discussion of the experience described immediately above, please indicate the 2004 business volumes your organization has generated in operating your benefit by completing the table below:

PHARMACY-RELATED ENTITIES INSURED PHARMACY BENEFITS (#1)		
Metric for Calendar Year 2004	Retail	Mail
Covered Lives (#2)		
Senior Lives (if available)		
Claims Processed or Total Utilization	Check: ☐ Claims Processed, or ☐ Total Utilization	Check: ☐ Claims Processed, or ☐ Total Utilization
Drug Spending Managed		
IF THE ENTITY UNDERWENT SIGNIFICANT CHANGE IN 2004, OR IT EXPECTS IN 2005 TO HAVE SUBSTANTIALLY DIFFERENT BUSINESS VOLUMES, PLEASE COMMENT BELOW AND PROVIDE 2005 PROJECTED VOLUMES IN ADDITION TO YOUR BUSINESS VOLUMES FOR 2004:		

#1 Exclusive of any prescription drug discount card programs

#2 a) Covered lives are discrete individuals for whom there is verifiable information / documentation that, on audit, would demonstrate their enrollment in the insured benefits program through either hard copy signed agreements, payment of insurance premiums, or some comparable verification. Covered lives are not demonstrated or accounted for by hits on a Web site or number of prescriptions filled or for which a claim was processed. Nor are covered lives demonstrated by counting signed agreements and multiplying by an average family size (if a **family** premium was paid, the "family" is 2 people; unless the organization can document additional family members are included).

b) To calculate covered lives, use most recent data. Applicants should pick a point in time within the previous 12 months and provide the number of unique lives. Please specify month for point in time used.

3.1.3 Licensure and Solvency

A. Complete the table below:

NOTE: APPLICANT CAN ONLY BE APPROVED FOR CONTRACT IF: ITEM #3 IS ANSWERED 'YES', OR ITEM #4 BELOW IS ANSWERED 'YES', AND CMS APPROVES THE REQUEST AND ITEM #7 IS ANSWERED 'YES' AND THE APPLICANT SATISFIES THE REQUIREMENT "B" BELOW, IF APPROPRIATE. ATTEST 'YES' OR 'NO' TO THE FOLLOWING STATE LICENSURE REQUIREMENTS.	YES	NO	DOES NOT APPLY
1. Applicant is licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in at least one State.			
2. Applicant is currently under some type of supervision, corrective action plan or special monitoring by the State licensing authority in any State.			
3. Applicant is licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which the Applicant proposes to offer Part D drug benefits.			
4. If Applicant does not meet Requirement #3, then Applicant has or will have completed and provided to CMS the *State Licensure Waiver Request Form* (Appendix IV) for each State in which it is not licensed but seeks to offer Part D drug benefits.			
5. If Applicant has provided the *State Licensure Waiver Request Form* to CMS, is it included in this application?			
6. If Applicant has provided the *State Licensure Waiver Request Form* to CMS, has it been sent in advance of this application to mailing address in waiver request form?			
7. If Applicant is seeking a waiver of the licensure requirement, the Applicant meets the CMS-published financial solvency and capital adequacy requirements.			

B. If the answer to item A1 above is "NO", the Applicant must submit the *Financial Solvency Documentation* (Appendix X), as a separate attachment.

C. If the answer to item A2 is "YES", include a separate attachment explaining the specific actions taken by the State license regulator. In these cases, CMS reserves the right to require the Applicant to demonstrate that it meets the CMS-published financial solvency and capital adequacy requirements.

D. If the answer to item A1 is "YES," then please provide documentation (e.g, licensing certificate or letter) from each State licensing authority of your organization's status as an entity licensed to bear risk.

3.1.4 Business Integrity

A. Complete the table below:

APPLICANT MUST ATTEST 'YES' TO THE FOLLOWING QUALIFICATION TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO THE FOLLOWING QUALIFICATION BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:	Yes	No
1. Applicant and its affiliated companies, subsidiaries or subcontractors, subcontractor staff, any member of its board of directors, and any key management or executive staff or any major shareholder agree that they are bound by 45 CFR Part 76 and attest that they are not excluded by the Department of Health and Human Services Office of the Inspector General or by the General Services		

B. List any past or pending, if known, investigations, legal actions, or matters subject to arbitration brought involving the Applicant (and Applicant's parent firm if applicable) and its subcontractors, including any key management or executive staff, or any major shareholders (5% or more), by a government agency (state or federal) over the past three years on matters relating to payments from governmental entities, both federal and state, for healthcare and/or prescription drug services. Provide a brief explanation of each action, including the following:

1) Legal names of the parties;
2) Circumstances;
3) Status (pending or closed);
4) If closed, provide the details concerning resolution and any monetary payments; and
5) Settlement agreements or corporate integrity agreements.

3.2 Benefit Design

3.2.1 Pharmacy and Therapeutics (P&T) Committee

A. Complete the form below:

INDICATE IF THE APPLICANT ANTICIPATES SUBMITTING A FORMULARY *Note: CMS is using this information to understand how many formularies it may need to review beginning April 18, 2005.*
Check Yes or No ☐ Yes ☐ No
If yes, indicate how many formularies you anticipate to submit:
If no, indicate if all drugs will have the same cost-sharing? ☐ Yes ☐ No

B. Complete the form below:

APPLICANT MUST ATTEST 'YES' TO THE FOLLOWING QUALIFICATION TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO THE FOLLOWING QUALIFICATION BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:	**YES**	**NO**
Applicant will submit a formulary, if answered "No" to "Indicate if all drugs will have the same cost-sharing" in 3.2.1 B above.		

C. Complete the form below:

PROVIDE THE NAMES OF THE MEMBERS OF YOUR ORGANIZATION'S P&T COMMITTEE. INDICATE WHICH MEMBERS ARE PRACTICING PHYSICIANS OR PRACTICING PHARMACISTS. FURTHER, INDICATE WHICH MEMBERS ARE EXPERTS IN THE CARE OF THE ELDERLY OR DISABLED, AND FREE OF ANY CONFLICT OF INTEREST WITH YOUR ORGANIZATION AND PHARMACEUTICAL MANUFACTURERS. (APPLICANTS SHOULD MARK THE INFORMATION AS PROPRIETARY.) ADD ADDITIONAL ROWS AS NECESSARY

	Practice/Expertise *Mark an 'X' in Appropriate Column*			**Free of Any Conflict of Interest** *Type Yes or No*	
Full Name of Member	Practicing Physician	Practicing Pharmacist	Elderly/Disabled Expert	With Your Organization?	With Pharmaceutical Manufacturers?

D. Complete the table below:

REPLY 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN. IF APPLICANT INDICATED IN 3.1.2.A, 'YES,' THAT APPLICANT IS PROVIDING A FORMULARY, THEN THE APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PDP CONTRACT. IF APPLICANT INDICATED NO IN 3.1.2.A, THAT IT IS NOT PROVIDING A FORMULARY AND REPLIES NO TO ANY OF THE ATTESTATIONS BELOW, THIS WILL NOT DISQUALIFY THE APPLICANT FROM A CONTRACT	YES	NO
1. Applicant will develop and use a P&T committee to develop and review the formulary and to ensure that the formulary is appropriately revised to adapt to both the number and types of drugs on the market. *Note: While the P&T committee may be involved in providing recommendations regarding the placement of a particular Part D drug on a formulary cost-sharing tier, the ultimate decision maker on such formulary design issues is the Part D plan, and that decision weighs both clinical and non-clinical factors.*		
2. Applicant's P&T committee will first look at medications that are clinically effective. When two or more drugs have the same therapeutic advantages in terms of safety and efficacy, the committee may review economic factors that achieve appropriate, safe, and cost-effective drug therapy.		
3. Applicant will assure that the P&T committee uses appropriate scientific and economic considerations to consider utilization management activities that affect access to drugs, such as access to non-formulary drugs, prior authorization, step therapy, generic substitution, and therapeutic interchange protocols.		
4. Applicant will adhere to P&T guidelines that will, from time to time, be promulgated with regard to such subject areas as membership, conflict of interest, meeting schedule, meeting minutes, therapeutic classes, drug review and inclusion, formulary management, utilization management and review, formulary exceptions, and educational programs for providers.		
5. Applicant's P&T committee will make a reasonable effort to review within 90 days, and will make a decision on each new chemical entity, and new FDA clinical indicators, within 180 days of its release onto the market, or a clinical justification will be provided if this timeframe is not met.		
6. Applicant's P&T committee will approve inclusion or exclusion of the therapeutic classes in the formulary on an annual basis.		
7. The majority of the membership of the Applicant's P&T committee shall be practicing physicians and/or practicing pharmacists.		
8. The membership of the Applicant's P&T committee will include at least one practicing physician and at least one practicing pharmacist who are free of conflict with respect to the Applicant organization and pharmaceutical manufacturers.		
9. The membership of the Applicant's P&T committee will include at least one practicing physician and at least one practicing pharmacist who are experts in the care of the elderly or disabled persons.		
10. Applicant's P&T committee will recommend protocols and procedures for the timely use of and access to both formulary and non-formulary drug products.		

3.2.2 Utilization Management Standards

A. Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN.	YES	NO
1. Applicant maintains policies and procedures to prevent over-utilization and under-utilization of prescribed medications, including but not limited to the following elements: • Compliance programs designed to improve adherence/persistency with appropriate medication regimens • Monitoring procedures to discourage over-utilization through multiple prescribers or multiple pharmacies • Quantity versus time edits • Early refill edits		
2. Applicant maintains methods to ensure cost-effective drug utilization management. Examples of these tools include, but are not limited to: • Step therapy • Prior authorization • Tiered cost-sharing		
3. Applicant makes enrollees aware of utilization management program requirements through information and outreach materials.		
4. Applicant develops incentives to reduce costs when medically appropriate such as, but not limited to encouragement of generic utilization.		
5. Applicant will report to CMS data for UM standards in the manner prescribed by CMS. (See Section 3.13 Reporting Requirements)		

3.2.3 Quality Assurance and Patient Safety

A. Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN.	YES	NO
1. Applicant establishes a quality assurance program that includes measures and reporting systems such as, but not limited to: • Reducing medication errors • Reducing adverse drug interactions		
2. Applicant performs drug utilization review at a minimum of what is specified in the regulation 42CFR 423.153 (c) (2) and (3).		
3. Applicant will ensure patient counseling is offered to enrollees, when appropriate.		
4. Applicant develops and implements internal medication error identification and reduction systems.		
5. Applicant ensures network pharmacies implement a method for maintaining up-to-date enrollee information such as, but not limited to: • Enrollee demographic information • Enrollee allergy information (drug and food)		

6. Applicant will report to CMS data for QA standards in the manner prescribed by CMS. (See Section 3.13 Reporting Requirements)		
7. Applicant will establish appropriate transition policies and procedures for beneficiaries on drug regimens that are not on the plan's Part D formulary. These policies and procedures must address all the elements specified in formulary transition guidance to be provided by CMS in early March.		
8. The Applicant agrees to submit to CMS on April 18, 2005 a description of the organization's approach to transitioning beneficiaries on drug regimens that are not on the plan's Part D formulary (see note below).		
9. Applicant will establish appropriate policies and procedures for addressing the immediate needs of enrollees who are LTC residents in situations where there is a disparity between the Part D requirements and the Medicare conditions of participation (COPs) for LTC facilities.		
10. The Applicant agrees to submit to CMS on April 18, 2005 a description of the organization's approach to address the immediate needs of enrollees who are LTC residents in situations where there is a disparity between the Part D requirements and the Medicare conditions of participation for LTC facilities. (see note below)		

NOTE: The answer to Item #8 and #10 will be collected in HPMS and should be submitted with the Applicant's formulary under the exception /notes transition word file provided in HPMS. The format will be delineated in HPMS user instructions that will be released in March.

3.2.4 Medication Therapy Management

A. Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN.	YES	NO
1. Applicant will develop and implement a Medication Therapy Management (MTM) Program designed to : • Ensure optimum therapeutic outcomes for targeted beneficiaries through improved medication use • For targeted beneficiaries, reduce the risk of adverse events, including adverse drug interactions		
2. Applicant will develop the MTM program in cooperation with licensed and practicing pharmacists and physicians.		
3. Applicant will target beneficiaries for enrollment in the MTM program based on all three of the following criteria: • Beneficiary must have multiple chronic diseases, such as diabetes, asthma, congestive heart failure, hyperlipidemia, and hypertension (list to be determined by plan); • Beneficiary must be taking multiple covered Part D medications (specifics to be determined by plan); and • Beneficiary must be identified as likely to incur annual costs for covered part D drugs that exceed $4,000.00		
4. Applicant will establish appropriate policies and procedures for their MTM program, including, but not limited to, services, payments and criteria used for identifying beneficiaries eligible for the MTM program.		
5. The Applicant agrees to submit to CMS on April 18, 2005 a description of their MTM program including, but not limited to, policies, procedures, services, payments and criteria provided in item #3 above used for identifying beneficiaries eligible for the MTM program.		
6. Applicant will coordinate the MTM program with the Medicare chronic care		

improvement program (CCIP) under section 1807 of the Social Security Act.		
7. Applicant will provide drug claims data to Chronic Care Improvement Programs (CCIP) for those beneficiaries that are enrolled in CCIPs in a manner specified by CMS.		
8. Applicant will report to CMS specified data on MTM programs in the manner prescribed by CMS. (See Section 3.13 Reporting Requirements)		
9. Applicant will establish an appropriate policy on how they will set MTM fees to pharmacists or others providing MTM services for covered Part D drugs. The policy will explain how the Applicant's fee or payment structure takes into account the resources used and the time required for by those providing MTM services.		
10. The Applicant agrees to submit to CMS on April 18, 2005 a description on how they will set MTM fees to pharmacists or others providing MTM services for covered Part D drugs. The policy will explain how the Applicant's fee or payment structure takes into account the resources used and the time required for by those providing MTM services.		

- **NOTE**: In providing responses to items 5 and 10 above follow these directions: The responses must be submitted to CMS by 5p.m. EST on April 18, 2005. The responses should be submitted to CMS by email in a word document **and** courier. The emailed response should be sent to drugbenefitimpl@cms.hhs.gov and the subject line must read Benefit Design Responses. Please include your contract number in the file name as well as in the cover page. The cover page should also specify that the responses are amendments to the March 23, 2005 application that are due on April 18, 2005. The cover page must be signed by an authorized representative, officer, chief executive officer, or general partner of the business organization that is applying for qualification to enter into a Part D contract with CMS. Clearly identify the element—3.2.4A5 or 3.2.4A10—in your response. The responses should be combined with additional responses required in Section 3.2.3. The responses must also be sent by courier to:

Centers for Medicare & Medicaid Services (CMS)
Marietta Mack
Mail Stop S1-05-06/Location S2-04-05
Attn: Benefit Design Responses
7500 Security Boulevard
Baltimore, Maryland 21244-1850

3.2.5 Electronic Prescription Program

A. Complete the table below:

APPLICANT MUST ATTEST 'YES' TO THE FOLLOWING QUALIFICATION TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO THE FOLLOWING QUALIFICATION BY PLACING A CHECKMARK IN THE RELEVANT COLUMN.	YES	NO
1. Once electronic prescribing standards are published and in effect, the Applicant agrees to have an electronic prescription program that supports electronic prescribing with pharmacies as well as physicians.		

3.3 Service Area/Regions

A. Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN.	YES	NO
1. Applicant will offer a PDP in at least one PDP region.		
2. For all PDP regions in which the applicant offers a PDP, the plan will provide coverage in entire region.		

B. Provide as an attachment, the table below, indicating the regions (including territories) you plan to serve. PDP region and Territory information may be found at the following website: ***www.cms.hhs.gov/medicarereform/mmaregions/pdpmaosum.asp***. Be sure to list both the region/territory name and associated number.

Region/Territory	Region/Territory Number

3.4 Pharmacy Access

A. Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:	YES	NO
1. Applicant agrees to permit in their plan networks any pharmacy that is willing to accept and meets the plans' standard terms and conditions. However, terms and conditions may vary, particularly with respect to payment terms to accommodate geographical areas (e.g. rural pharmacies) or different types of pharmacies (e.g. mail order and retail), provided that all similarly-situated pharmacies are offered the same standard terms and conditions.		
2. Applicant agrees not to require a pharmacy to accept insurance risk as a condition of participation in the PDP's network		
3. Applicant's network pharmacy contracts contain provisions governing submitting claims to a real-time claims adjudication system		
4. Applicant's network pharmacy contracts contain provisions governing providing access to negotiated prices		
5. Applicant's network pharmacy contracts contain provisions regarding charging/applying the correct cost-sharing amount, including that which applies to individuals qualifying for the low-income subsidy		
6. Applicant's network pharmacy contracts contain provisions governing informing the Part D enrollee at the point of sale (or at the point of delivery for mail order drugs) of the lowest-priced, generically equivalent drug, if one exists for the beneficiary's prescription, as well as any associated differential in price.		

Note: While CMS realizes that contracts with Indian Health Services, Indian Tribes and Tribal organizations and Urban Indian Organization (I/T/U), Federally Qualified Health Centers (FQHC)

and Rural Health Centers (RHC) may be counted for purposes of meeting the pharmacy access standards, it should be noted that contracts with these pharmacies may not be used as a substitution for inclusion in plan networks of retail pharmacies.

B. Provide as an attachment the unsigned standard terms and conditions offered in the contract (or addenda to the contract) for each of the following types of pharmacies: Retail, Mail Order, Home Infusion, I/T/U, and Long-Term Care. The mail order contract is only necessary if the plan is offering mail order. If there are several different types of standard terms and conditions for the same type of pharmacy, please provide all versions. For example, if different terms for retail pharmacies apply depending upon geographic location, all standard terms must be provided.

- Contracts (or addenda to contracts) must contain all of the required provisions described in 3.1.1F for contracts or letters of agreement with the Applicant's subcontractors except for the following numbers 1, 3, 5, 6, 7 and 14.

- No signature pages need be submitted at this time, but each Applicant must make a complete file of such pages available for inspection upon CMS' request.

C. Provide electronic lists of the Pharmacy Access Contract Citations demonstrating that the applicable requirements in 3.1.1F, 3.4A, 3.4.5 and 3.4.6B and any other requirements in Appendix XIII are included in such contracts. Submit this data by creating a spreadsheet in Microsoft Excel that mimics Appendix XIII. Provide this attachment on a CD as instructed in Section 2.6. This information must be clearly labeled to indicate to which party of the joint enterprise the information pertains.

3.4.1 Retail Pharmacy

A. Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:	YES	NO
1. Applicant agrees to meet the CMS Standards for Convenient Access [§423.120 (a) (1) and (2)] as early as March 23, 2005 but no later than July 15, 2005 (See Appendix VII)		
2. Applicant agrees that if these pharmacy access standards are not fully met by March 23, 2005, that applicant will resubmit the analysis in Section 3.4.1 (A) on August 1, 2005.		
3. Applicant agrees to permit enrollees to receive benefits which may include a 90-day supply of covered Part D drugs at any of its network pharmacies that are retail pharmacies instead of at a network mail-order pharmacy.		

Note: Concerning the rural access standard, there may be several States for which the standard will be impossible or impracticable to meet given the lack of infrastructure. CMS will identify these States and make an exception to meeting this requirement based on analysis of the number of retail pharmacies in the State, the State's Medicare population and the access ratios across plans that include these States in their service area.

B. Using Geographic Information Systems (GIS) or similar software, demonstrate in the March 23, 2005 application, the applicant's pharmacy access ratios for their intended

service area, using only the pharmacies for which contracts are executed for the Part D benefit. Please note that:

- As defined in 42 CFR 423.100:
  - urban areas are five-digit ZIP Codes in which the population density is greater than 3,000 persons per square mile;
  - suburban areas are five-digit ZIP Codes in which the population density is equal to or greater than 1,000 persons per square mile and less than or equal to 3,000 persons per square mile; and
  - rural areas are five-digit ZIP Codes in which the population density is less than 1,000 persons per square mile.

Note: If the convenient access standards are not satisfied on the March 23, 2005 application, then these analyses must also be submitted to CMS on August 1 2005.

- The demonstration of pharmacy access must be based on a computation using of beneficiary counts by Zip Code provided by CMS at http://www.cms.hhs.gov/pdps. (File name: "MCareEnrbyZip062004.zip"). Due to periodic changes in ZIP codes, CMS recognizes that some ZIP codes in the data provided by CMS may not "map" to current ZIP code listings for your service area. These ZIP codes may be excluded from your summary analyses.

- Maps and tables must be generated for the Applicant's entire service area using the locations for the pharmacy network under contract for the Part D benefits and the standard beneficiary file provided to bidders at http://www.cms.hhs.gov/pdps. This network analysis may include only retail (non-mail-order) pharmacies, I/T/U pharmacies, and pharmacies operated by a FQHC or RHC as provided in Section 423.120 (a) (1) and (a) (2). Applicants are responsible for insuring the urban, suburban, and rural definitions used in their analyses conform with the definitions for these areas as provided in 42 CFR 423.100. Most network access analysis programs default to classifications consistent with the regulatory requirements. Upon request by an applicant, CMS will provide urban, suburban, and rural classifications by beneficiary Zip Code based on the relation of CMS beneficiary ZIP codes to ZIP code Tabulation Areas (ZCTAs). The population densities used in this file are based on the U.S, Census Bureaus ZCTA Gazetteer file.[1] Use of this more detailed file by applicants is not required. This file is available to applicant organizations that require further detail for mapping classification purposes.[2]

- Maps and tables generated by the mapping software must include aggregate urban, suburban, and rural ratios for the entire service area to be served by the PDP sponsor, as well as urban, suburban, and rural ratios for each region, state, and county included under the program.

C. Provide an electronic list of all contracted retail pharmacy outlets included in the analysis. *Submit this data by creating a spreadsheet in Microsoft Excel that mimics the table below. Provide this attachment on a CD as instructed in Section 2.6. Submit this list to CMS with the March 23, 2005 application and again on August 1, 2005 if there are changes.*

Full Name	Full Address	Pharmacy	Contact	NABP	Pharmacy Type

[1] See http://www.census.gov/geo/www/gazetteer/places2k.html

[2] Requests for this file should be submitted to dhodges@cms.hhs.gov with the subject line**: ZIP Classification File Request**

of Pharmacy	Street	City	State	Zip	Telephone Number		Number	*Mark Preferred (P) or Non-Preferred (N)*

3.4.2 Out of Network Pharmacy

A. Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:	YES	NO
1. Applicant agrees to ensure that enrollees have adequate access to covered Part D drugs dispensed at out-of-network pharmacies when an enrollee cannot reasonably be expected to obtain such drugs at a network pharmacy and provided such enrollees do not access Part D drugs at an out-of-network pharmacy (or a physician's office) on a routine basis.		
2. Applicant agrees to ensure that enrollees have adequate access to covered Part D drugs dispensed at physician offices for covered Part D drugs that are appropriately dispensed and administered in physician offices (e.g. Part D-covered vaccines).		
3. Applicant agrees to abide by Section 423.124(b) relating to the financial responsibility for out-of-network access to covered Part D drugs and may require its Part D enrollees accessing covered Part D drugs to assume financial responsibility for any differential between the out-of-network pharmacy's usual and customary price and the PDP sponsor plan allowance, consistent with the requirements of § 423.124(d) (2) (i) (B) and § 423.124(e).		
4. Applicant agrees to develop policies and procedures governing reasonable rules to appropriately limit out-of-network access and to include at least the following: Beneficiary is guaranteed out-of-network access when: • Traveling outside his or her plan's service area and runs out of or loses his or her covered Part D drugs or becomes ill and needs a covered Part D drug, and cannot access a network pharmacy; • Not able to obtain a covered Part D drug in a timely manner within his or her service area because, for example, there is no network pharmacy within a reasonable driving distance that provides 24/7 service; • Filling a prescription for a covered Part D drug and that particular drug (for example, an orphan drug or other specialty pharmaceutical) is not regularly stocked at an accessible network retail or mail-order pharmacy; • Provided covered Part D drugs dispensed by an out-of-network institution-based pharmacy while a patient is in an emergency department, provider-based clinic, outpatient surgery, or other outpatient setting.		

3.4.3 Mail Order Pharmacy

A. Complete the table below:

APPLICANTS MAY OFFER A MAIL ORDER OPTION IN ADDITION TO THEIR CONTRACTED PDP PHARMACY NETWORK BUT MAIL ORDER PHARMACIES DO NOT COUNT IN MEETING NETWORK ADEQUACY STANDARDS. INDICATE 'YES' OR 'NO' WHETHER SUCH MAIL ORDER PHARMACY IS OFFERED.	YES	NO
1. Applicant will offer mail order pharmacy as part of its Part D plans		

B. Provide an electronic list with the March 23, 2005 application of all Applicant-owned and/or contracted mail order pharmacies to provide Part D benefits – only if your PDP will

include them. ***Submit this data by creating a spreadsheet in Microsoft Excel that mimics the table below. Provide this attachment on a CD as instructed in Section 2.6. Provide an updated list on August 1,2005 if there are changes.***

Full Name of Pharmacy	Full Address				Pharmacy Telephone Number	Contact	NABP Number	Pharmacy Type *Mark Preferred (P) or Non-Preferred (N)*
	Street	City	State	Zip				

3.4.4 Home Infusion Pharmacy

A. Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:	**YES**	**NO**
1. Applicant agrees to provide adequate access to home infusion pharmacies.		
2. If applicant does not provide the analysis required in "B" below with the March 23rd application, Applicant agrees to provide it on than August 1, 2005.		
3. Applicant agrees that its network contracts will address Part D drugs delivered in the home setting through home infusion therapy pharmacies.		

B. Provide a map and table generated by mapping software of the dispersion of the Applicant's contracted home infusion pharmacies, as well as the ratios of beneficiaries to these pharmacies for the entire service area and for each region, state and county. Use the beneficiary counts by Zip Code provided by CMS at http://www.cms.hhs.gov/pdps. (File name: "MCareEnrbyZip062004.zip" **in your analysis. Based on the findings in this map and table, describe how the home infusion pharmacies in the Applicant's network adequately provides the Part D benefit to the beneficiaries that the Applicant intends to enroll throughout its proposed service area. Submit this information to CMS with the March 23, 2005 application or on August 1, 2005. Note: Documentation for Home Infusion Access (3.4.4 B) and Home Infusion Pharmacy List (3.4.4 C) must be submitted at the same time.**

C. Provide an electronic list of all contracted Home Infusion Pharmacies to provide Part D benefits. ***Submit this data by creating a spreadsheet in Microsoft Excel that mimics the table below. Provide this attachment on a CD as instructed in Section 2.6. Submit this list when the response to 3.4.4B is provided to CMS.***

Full Name of Pharmacy	Full Address				Pharmacy Telephone Number	Contact	NABP Number	Pharmacy Type *Mark Preferred (P) or Non-Preferred (N)*
	Street	City	State	Zip				

3.4.5 Long -Term Care (LTC) Pharmacy

A. Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:	**YES**	**NO**
1. Applicant agrees to offer standard contracting terms and conditions to all long-term care pharmacies in its service area. These terms and conditions must include all the		

performance and service criteria for long-term care pharmacies that CMS will specify in a future Long-Term Care Guidance document		
2. Applicant agrees to recognize the CMS special election period (SEP) or open enrollment period for institutionalized individuals (OEPI) for Part D drug plan enrollment and disenrollment for beneficiaries entering, living in, or leaving a long-term care facility.		
3. Applicant agrees that if contracts with long-term care pharmacies are not fully executed by March 23, 2005, that applicant will resubmit the analysis requested below on August 1, 2005.		
4. Applicant agrees that it will contract with a sufficient number of LTC pharmacies to provide all of the plan's institutionalized enrollees convenient access to their Part D benefit.		
5. If applicant does not provide the analysis required in ""C" below with the March 23rd application, applicant agrees to provide it on August 1, 2005.		

Note: CMS will release Long-Term Care Guidance in early March, 2005. This document will contain a list of Performance and Service Criteria, as referenced in item #1 of the above table. Applicants will be required to incorporate, at a minimum, those criteria in any LTC pharmacy network contract.

B. Provide a work plan with the March 23, 2005 application, outlining the Applicant's strategy for completing contracting with long-term care pharmacies in proposed service area by July 15, 2005 and in time to submit access information by August 1, 2005. The work plan should include (but is not limited to) activities associated with and target dates for the following major milestones: identification of LTC pharmacies, conducting outreach, contract offering, arrangements for discussion/negotiation, anticipated contract closure, tracking progress and assessing progress to modify approach as necessary.

C. On August 1, 2005 provide an electronic list of all contracted Long-Term Care Pharmacies to provide Part D benefits. *Submit this data by creating a spreadsheet in Microsoft Excel that mimics the table below. Provide this attachment on a CD as instructed in Section 2.6*

Full Name of Pharmacy	Full Address				Pharmacy Telephone Number	Contact	NABP Number	Pharmacy Type *Mark Preferred (P) or Non-Preferred (N)*
	Street	City	State	Zip				

D. Describe how the long-term care pharmacies in the Applicant's network represents a sufficient number of long-term care pharmacies to provide all of the plan's institutionalized enrollees with convenient access to their Part D benefit..

3.4.6 Indian Health Service, Indian Tribe and Tribal Organization, and Urban Indian Organization (I/T/U) Pharmacy

A. Complete the table below:

APPLICANT MUST ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN TO BE APPROVED FOR A PDP CONTRACT.:	YES	NO
1. Using the list of I/T/U pharmacies provided at http://www.cms.hhs.gov/pdps or http://www.cms.hhs.gov/aian/, indicate whether your service area includes at least one I/T/U pharmacy.		

B. Complete the table below:

NOT ALL PDP REGIONS HAVE I/T/U PHARMACIES. IF THE APPLICANT'S SERVICE AREA COVERS ANY REGION THAT INCLUDES I/T/U PHARMACIES, THEN THE APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PDP CONTRACT. IF ALL OF THE APPLICANT'S SERVICE AREA DOES NOT INCLUDE I/T/U PHARMACIES, THEN THE APPLICANT MAY ANSWER 'NO' AND STILL BE APPROVED FOR A PDP CONTRACT SINCE THESE REQUIREMENTS DO NOT APPLY. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:	**YES**	**NO**
1. Applicant agrees to offer standard terms and conditions that conform to the model contract addenda provided by CMS to all I/T/U pharmacies in its service area. These model contract addenda are located at http://www.cms.hhs.gov/pdps/ and http://www.cms.hhs.gov/aian/. The model contract addenda account for differences in the operations of I/T/U pharmacies and retail pharmacies.		

Note: Information for Part D Sponsors on Contracting with Indian Health Care Providers is located at: http://www.cms.hhs.gov/pdps/ and http://www.cms.hhs.gov/aian/.

C. Provide below a work plan with the March 23, 2005 application outlining the Applicant's strategy for completing contracting with I/T/U pharmacies in proposed service area by July 15, 2005 and in time to submit an electronic I/T/U Pharmacy list (3.4.5 D) on August 1, 2005. The work plan should include (but is not limited to) activities associated with and target dates for the following major milestones: identification of I/T/U pharmacies, conducting outreach, contract offering, arrangements for discussion/negotiation, anticipated contract closure, tracking progress and assessing progress to modify approach as necessary. Also, included in this work plan should be a period not to exceed 45 days for an I/T/U pharmacy to enter into a contract with the plan once the contract has been offered to the pharmacy.

D. On August 1,2005, provide an electronic list (by State) for each I/T/U Pharmacy. *Submit this data by creating a spreadsheet in Microsoft Excel that mimics the table below. Provide this attachment on a CD as instructed in Section 2.6.*

Full Name of Pharmacy	Full Address				Phone Number	Contact	NABP or ASEP No.	Pharmacy Type *Mark Preferred (P) or Non-Preferred (N)*	Status of Contract *Mark with an "X"*			
	Street	City	State	Zip					Date of Offer	Accepted	Declined	Under Negotiation

3.5 Enrollment and Eligibility

A. Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO E ACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:	**YES**	**NO**

1. Applicant will permit the enrollment of all Medicare beneficiaries who are eligible for Part D and reside in the PDP service area during allowable enrollment periods according to CMS requirements to be issued in April 2005 .		
2. Applicant agrees to limit PDP enrollment to eligible Medicare beneficiaries who reside in the plan service area according to CMS requirements to be issued in April 2005.		
3. Applicant will accept auto-enrollments in accordance with procedures adopted by CMS for certain low-income beneficiaries who have failed to enroll in a Part D plan offering qualified prescription drug coverage.		
4. Applicant will not enroll any beneficiary who is already enrolled in a Part D plan or, who is identified as a member of a Medicare Advantage plan (other than a private fee-for-service plan that does not provide qualified prescription drug coverage or an MSA plan). Applicant does not enroll beneficiaries except during allowable enrollment periods.		
5. Applicant will accept enrollments from beneficiaries beginning November 15, 2005.		
6. Applicant will collect and transmit data elements specified by CMS for the purposes of enrolling and disenrolling beneficiaries in accordance with timeframes specified in CMS instructions.		
7. Applicant will develop and operate a process for enrolling Medicare beneficiaries in the PDP that includes: communicating with beneficiaries who are applying for enrollment in the PDP within timeframes specified by CMS in requirements to be issued in April 2005; initiating appropriate follow up with beneficiaries who have incomplete enrollment applications; and making enrollments effective according to the effective date policy associated with the enrollment period in which the enrollment is received.		
8. Applicant will permit voluntary disenrollments only during allowable periods as specified in CMS requirements to be issued in April 2005.		
9. Applicant will accept and process disenrollment requests from beneficiaries, communicate these requests to CMS, and make the disenrollment effective according to the effective date policy associated with the enrollment period in which the disenrollment request is received.		
10. Applicant will develop policies and procedures for addressing beneficiary requests for a Special Enrollment Period and verifying a beneficiary's eligibility for a Special Enrollment Period.		
11. Applicant will notify beneficiaries in the event of a contract termination of the termination and alternatives for obtaining prescription drug coverage under Part D in accordance with Part 423 regulations.		
12. Applicant will develop and implement by November 15, 2005, policies and procedures (including appropriate notice and due process requirements) for optional involuntary disenrollment as permitted by CMS.		
13. Applicant will provide PDP identification card to enrollees by January 1, 2006, consistent with CMS requirements to be issued in April 2005.		

3.6 Grievances

A. Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN.	YES	NO
1. Applicant will establishe and maintain a process designed to track and address enrollees' grievances and assures that they will adopt appropriate timelines, policies and procedures and train the relevant staff and subcontractors on such policies and procedures in accordance with 42CFR 423.564.		

2. Applicant will make enrollees aware of the grievance process through information and outreach materials.		
3. Applicant will accept grievances from enrollees at least by telephone and in writing (including facsimile)		
4. Applicant will maintain, and provides upon request by CMS access to records on all grievances received both orally and in writing, that includes, at a minimum: • Date of receipt of the grievance • Mode of receipt of grievance (i.e. fax, telephone, letter, etc.) • Person or entity that filed the grievance • Subject of the grievance • Final disposition of the grievance • Date the enrollee was notified of the disposition		

Note: A grievance is any complaint or dispute, other than one that involves a coverage determination, expressing dissatisfaction with any aspect of a PDP sponsor's operations, activities, or behavior, regardless of whether remedial action is requested. Examples of subjects of a grievance include, but are not limited to:

- Timeliness, appropriateness, access to, and/or setting of services provided by the PDP sponsor
- Concerns about waiting times, demeanor of pharmacy or customer service staff
- A dispute concerning the timeliness of filling a prescription or the accuracy of filling the prescription.

3.7 Exceptions and Appeals

A. Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN.	YES	NO
1. Applicant will adopt policies and procedures for beneficiary coverage determination, exceptions, and appeals consistent with 42 CFR §423 subpart M.		
2. Applicant will assure that it will comply with 423.578(a) and 423.578 (b) which require a PDP sponsor to grant a tiering or off –formulary exception whenever it determines an exception is medically appropriate because the preferred drug (or on-formulary drug in the case of a formulary exception request): (a) would not be as effective for the enrollee as the requested drug; or (b) would have adverse effects for the enrollee, or (c) both.		
3. Applicant will make its enrollees aware of the coverage determination, exceptions, and appeals process through information provided in the Evidence of Coverage and outreach materials.		
4. Applicant will establish and maintain a process designed to track and address in a timely manner enrollees' exceptions requests, requests for coverage determination, re-determination, requests for reconsideration by the Independent Review Entity (IRE), and requests for review by the Administrative Law Judge (ALJ) received both orally and in writing, that includes, at a minimum: • Date of receipt; • Date of any notification; • Disposition of request; and • Date of disposition		
5. Applicant will make available to CMS upon CMS request, exception and appeals records.		

3.8 Coordination of Benefits

A. Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:	YES	NO
1. Applicant develops and operates a system for collecting information from enrollees about enrollees' other health insurance, including whether such insurance covers outpatient prescription drugs.		
2. Applicant is familiar with rules that determine when other payers are primary or secondary to Medicare.		
3. Applicant will permit SPAPs and other third party payers to coordinate benefits as required by the regulations in Subpart J, Part 423, 42 CFR. For example, an SPAP might pay the premium for supplemental benefits on behalf of a beneficiary		
4. Applicant will abide by the guidance of CMS regarding the Coordination of Benefit requirements to be released July 1, 2005.		
5. Applicant agrees to pay user fees as required under 423.6 and may be required in 423.464 (c).		
6. Applicant agrees not to impose fees on SPAPs or other third-party insurers unrelated to the cost of coordination of benefits.		

B. Describe below your organization's system for collecting and updating enrollee information concerning their other health insurance.

C. Describe below your organization's current system for coordinating payment of claims by enrollees' other health insurance, including SPAPs.

3.9 Tracking Out-of Pocket Costs (TrOOP)

A. Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:	YES	NO
1. Applicant will track each enrollee's true out of pocket (TrOOP) costs reflecting the amount the enrollee has spent out of pocket during a program year on covered Part D drugs.		
2. Applicant will accept data concerning third party payers in a format to be specified by CMS no later than April 2005 for use in the Applicant's TrOOP calculation.		
3. Applicant will provide each enrollee with a report on their TrOOP status at least monthly.		
4. Applicant will provide enrollees daily access to their current TrOOP status through		

the organization's toll-free customer service phone number.		
5. In the event of disenrollment, Applicant agrees to provide TrOOP status of the beneficiary as of the effective date of the disenrollment.		

3.10 Marketing/Beneficiary Communications

A. Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN.	YES	NO
1. Applicant will make available to beneficiaries only those marketing materials that comply with CMS' marketing guidelines and complied with CMS approval procedures in accordance with CMS guidelines and regulations to be issued in April 2005.		
2. Annually and at the time of enrollment, the Applicant agrees to provide enrollees information about the following PDP features, as described in the marketing guidelines: • Enrollment Procedures; • Beneficiary Procedural Rights; • Potential for Contract Termination; • Benefits; • Types of Pharmacies in the Pharmacy Network; • Out-of-network Pharmacy Access; • Formulary; • Premiums; • Service Area; The Applicant further agrees to provide general coverage information, as well as information concerning utilization, grievances quality assurance, and sponsor financial information to any beneficiary upon request.		
3. Applicant will maintain a toll-free customer service call center that is open during usual business hours and provides customer telephone service in compliance with standard business practices. This means that the Applicant must comply with at least the following: • Call center operates during normal business hours, but not less than Monday through Friday from 8:00 AM to 4:30 PM for those time zones in which the Applicant offers a PDP (Drug Card Standard); • Eighty percent of all incoming customer calls are answered within 30 seconds; • The abandonment rate of all incoming customer calls does not exceed 5 percent; • Call center provides thorough information about the PDP benefit plan, including co-payments, deductibles, and network pharmacies; • Call center features an explicit process for handling customer complaints; and • Call center shall provide service to non-English speaking and hearing impaired beneficiaries		
4. Applicant will operate an Internet Web site that a) provides all the information described in Item #2 of this table, b) describes the Applicant's PDP's current formularies, and c) provides 60-days' notice to potential and current plan enrollees of the removal or change in the tier placement of any drug on the plan's formulary.		
5. Applicant will provide its plan enrollees, in a form understandable to enrollees and on at least a monthly basis for those months in which the enrollees use their Part D benefits, an explanation of benefits that states a) the item or service for which payment was made; b) notice of the enrollee's right to an itemized statement; c) a year-to-date statement of the total Part D benefits provided in relation to deductibles, coverage limits, and annual out-of-pocket thresholds; d) cumulative year-to-date total		

of incurred costs; and e) applicable formulary changes.		

3.11 Provider Communications

A. Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:	YES	NO
1. Applicant operates toll-free call center to respond to inquiries from pharmacies and providers regarding the Applicant's Medicare prescription drug benefit. Inquiries will concern such operational areas as claims processing, benefit coverage, claims submission, and claims payment		

3.12 Compliance Plan

A. Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:	YES	NO
1. Applicant will implement a compliance plan that consists of written policies, procedures, and standards of conduct articulating your organization's commitment to abide by all applicable Federal and State standards.		
2. Applicant will implement a compliance plan that designates a compliance officer and compliance committee accountable to senior management.		
3. Applicant will implement a compliance plan that includes effective training and education between the compliance officer, organization employees, contractors, agents, and directors.		
4. Applicant will implement a compliance plan that includes effective lines of communication between the compliance officer and organization employees, contractors, agents and directors and members of the compliance committee.		
5. Applicant will implement a compliance plan that includes disciplinary standards that are well-publicized.		
6. Applicant will implement a compliance plan that includes procedures for internal monitoring and auditing.		
7. Applicant will implement a compliance plan that includes procedures for ensuring prompt response to detected offenses and development of corrective action initiatives, relating to the Applicant's contract as a Part D sponsor.		
8. Applicant will implement a compliance plan that includes a comprehensive plan to detect, correct, and prevent fraud, waste and abuse.		

Note: CMS recommends to Applicants that they include in their compliance plans provisions requiring the reporting of fraud and abuse to the appropriate government authority. Part D sponsors that self-report violations will continue to receive the benefits of voluntary self-reporting found in the False Claims Act and Federal sentencing guidelines.

Note: CMS acknowledges that prospective PDP sponsors may not have time to develop a satisfactory compliance plan prior to the due date for this application. Therefore, the Applicant must provide brief responses to the following elements as part of its application, which may reflect a finalized compliance plan or work in progress toward a final plan.

B. Describe below the fraud and abuse section of your organization's compliance plan as it would apply to the operation of your Medicare prescription drug benefit plan:

C. Provide a copy of your organization's policies, procedures, and standards of conduct that articulate your organization's commitment to detecting and preventing waste, fraud and abuse among your Part D plans and those with whom you contract. *Provide this attachment on a CD as instructed in Section 2.6.*

D. Identify below your organization's compliance officer, provide his/her resume, and describe his/her place in your organization (i.e., to whom does he/she directly report?):

E. Describe below your organization's fraud and abuse training program, including the frequency of such training:

F. Describe below how standards of conduct and procedures for reporting potential fraud and abuse issues are publicized within your organization:

G. Describe below your procedures for internal monitoring and auditing to protect the Medicare Trust Fund from waste, fraud and abuse in the Part D program (including frequency and responsible staff):

H. Describe below the process your staff will follow to identify possible offenses and how these matters would be reported to CMS and/or its contractors:

3.13 Reporting Requirements

A. Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:	YES	NO
BUSINESS TRANSACTIONS AND FINANCIAL REQUIREMENTS		
1. Applicant will report, consistent with 42 CFR §423.514(b), information related to significant business transactions between the Part D plan sponsor and a party in interest within 120 days of the end of each fiscal year. This qualification includes combined financial statements, where required under 42 CFR §423.514(c).		
2. Applicant will notify CMS of any loans or other special financial arrangements made with contractors, subcontractors, and related entities as that term is defined in 42 CFR §423.501.		
3. Applicant will submit audited financial statements to CMS annually.		
CLAIMS DATA		
4. The Applicant or the Applicant's representative, such as a third party administrator (TPA), has data management processes and data systems capable of accomplishing collection of data in either an NCPDP or X12 format. Data to be collected will encompass quantity, type, and costs of pharmaceutical prescriptions filled for enrollees. The plan must link this information to Medicare beneficiary identification numbers (HIC#s).		
5. The Applicant or the Applicant's representative, such as a third party administrator (TPA), has data management processes and data systems capable of accomplishing submission of prescription drug claims information for Medicare enrollees for every		

Part D drug prescription in the format required by CMS, using batch submission processes. Data to be submitted will encompass quantity, type and costs of pharmaceutical prescriptions filled for enrollees. The plan must link this information to Medicare beneficiary indentification numbers (HIC#s).		
6. The Applicant or the Applicant's representative, such as a third party administrator (TPA), has data management processes and data systems capable of accomplishing submission of data to CMS via the Medicare Data Communications Network (MDCN) as referenced in Section 2.8.		
7. The Applicant or the Applicant's representative, such as a third party administrator (TPA), has data management processes and data systems capable of accomplishing performance of data edit and quality control procedures to ensure accurate and complete prescription drug data.		
8. The Applicant or the Applicant's representative, such as a third party administrator (TPA), has data management processes and data systems capable of accomplishing correction of all data errors identified by CMS.		
9. The Applicant or the Applicant's representative, such as a third party administrator (TPA), has data management processes and data systems capable of accomplishing collection of data for dates of service within the coverage period with a 3-month closeout window for the submission of remaining unreported claims data.		
10. The Applicant or the Applicant's representative, such as a third party administrator (TPA), has data management processes and data systems capable of accomplishing provision of additional information for the purposes of reconciliation of risk factors, low income subsidy payments, reinsurance payments, and risk corridor as required by CMS.		
11. Applicant will send and receive claims data for third party payers from the CMS contractor that will serve as the clearinghouse for all Part D beneficiary outpatient drug claims.		
REBATE DATA		
12. The Applicant or the Applicant's representative has accounting systems capable of accomplishing the provision of documentation, as specified by CMS, to support the accuracy and completeness of data. Documentation will be provided to CMS in response to an audit-based request.		
13. The Applicant will report rebate dollars on a quarterly basis at the manufacturer/brand name level (unique strength and package size not required) in the manner specified by CMS.		
14. The Applicant or the Applicant's representative has accounting systems capable of accomplishing the production of financial reports to support rebate accounting. The rebate accounting must allow for step-down cost reporting in which rebates received at the aggregate level may be apportioned down to the level of plan enrollees.		
UTILIZATION MANAGEMENT DATA		
15. The Applicant will report quarterly the generic dispensing rate which is calculated as the number of generic drugs dispensed to the patient divided by the total number of drugs dispensed within a given time period.		
16. If formulary management tools include prior authorization the Applicant will report to CMS on a quarterly basis information about the use of that tool. Such information may include, but is not limited to: • The number of pharmacy transactions denied due to the need for prior authorization • The number of prior authorizations requested • The number of prior authorizations approved		
EXCEPTIONS AND APPEALS		
17. The Applicant will report at a frequency specified by CMS the following information related to exceptions and appeals that may include, but is not limited to: • # Step edits attempted • # Step edits failed • # Appeals		

• # Appeals overturned		
MEDICATION THERAPY MANAGEMENT DATA		
18. The Applicant will report semi-annually (by dates to be published by CMS each year) information related to the implementation of its Medication Therapy Management program that may include, but is not limited to: • # Beneficiaries targeted • # Beneficiaries participating • # Beneficiaries declined • Total drug cost for patients in MTM on a per enrolled MTM beneficiary per month basis		
OTHER DATA		
19. The Applicant will provide CMS with routine administrative reports (pursuant to 42 CFR 423.514 (a)) on a variety of measures that concern the Applicant's performance in the administration of the Part D benefit. Such reports shall be submitted according to instructions issued with timely notice by CMS.		
SUPPORTING WWW.MEDICARE.GOV		
20. The Applicant will submit pricing and pharmacy network information to be publicly reported on www.medicare.gov in order to provide Medicare beneficiaries with necessary information regarding prescription drug costs under the respective plans. Details regarding this data requirement will be posted on www.cms.hhs.gov by April 20, 2005.		
CONFLICT OF INTEREST		
21. The Applicant will provide financial and organizational conflict of interest reports to CMS, pursuant to instructions to be issued by CMS.		

Note: Further detail on our approach to monitoring and oversight, including the exact reporting measures will be posted on the CMS website not later than April 2005. Price Compare requirements will be posted in May 2005.

3.14 Data Exchange Between PDP and CMS

A. Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:	**YES**	**NO**
HPMS		
1. Applicant will use HPMS to communicate with CMS in support of the application process, formulary submission process, bid submission process, ongoing operations of the Part D program, and reporting and oversight activities. PDPs are required to secure access to HPMS in order to carry out these functions.		
2. Applicant will establish access to HPMS according to the instructions in *Accessing CMS Systems* (Appendix II). *NOTE: CMS requires that applicants submit HPMS user access request forms at the time of submission of the notice of intent to apply. Establishing timely connectivity will ensure that applicants have a sufficient amount of time to prepare and submit formularies to HPMS by April 18, 2005 and plan bids to HPMS by June 6, 2005.*		
ENROLLMENT & PAYMENT		

3. Applicant will establish connectivity to CMS via the AT&T Medicare Data Communications Network (MDCN).		
4. Applicant will submit test enrollment and disenrollment transmissions.		
5. Applicant will obtain CMS User ID and Password.		
6. Applicant will submit enrollment, disenrollment and change transactions to communicate membership information to CMS each month.		
7. Applicant will reconcile PDP data to CMS enrollment/payment reports within 45 days of availability.		
8. Applicant will submit enrollment/payment attestation forms within 45 days of CMS report availability.		

3.15 Privacy

A. Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:	YES	NO
1. Applicant agrees not to use the Social Security Number (SSN) or Medicare ID Number on the enrollees' identification cards.		
2. Applicant will notify each beneficiary, prior to enrollment or at the time of enrollment, of expected uses and disclosures of the beneficiary's protected health information, as well as the beneficiary's rights and Applicant's duties with respect to such information. Such notice is to be provided in plain language containing sufficient detail to advise the beneficiary of the uses and disclosures permitted or required under applicable law.		
3. Applicant will obtain written authorization for all uses and disclosures of protected health information not otherwise permitted under the HIPAA Privacy Rule. Beneficiaries may authorize disclosure of their protected health information to a third party, such as their employer.		
4. Applicant will ensure that all its agents and subcontractors comply with all the requirements of 45 CFR Parts 162 and 164 when performing functions on the Applicant's behalf.		
5. Applicant will comply with the requirements applicable to covered entities in 45 CFR Part 160 relating to use of national identifiers.		
6. Applicant will comply with any applicable standards, implementation specifications, and requirements in the Standards for Electronic Transactions under 45 CFR Parts 160 and 162 subparts I *et seq*.		

3.16 Security and Record Retention

A. Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:	YES	NO
SECURITY		
1. Applicant attests that at least one of the following conditions is true: a) By completing the *HIPAA Security Attestation Statement,* (Appendix V), as of the initial enrollment		

date, appropriate administrative, technical, and physical safeguards will be in place to protect the privacy of protected health information in accordance with 45 CFR §164.530(c), and that Applicant will meet the standards, requirements, and implementation specifications as set forth in 45 CFR part 164, subpart C, the HIPAA Security Rule, prior to beginning enrollment of beneficiaries; or b) If Applicant is unable to provide this attestation, Applicant provides a plan for coming into compliance with the specifications as set forth in the Security Rule as requested in 3.16B below. Applicant is encouraged, but not required, to use the Information Security Program references as provided by the National Institute of Standards and Technology (NIST) found at www.nist.gov in describing your efforts to implement reasonable security measures.		
RECORD RETENTION		
2. The Applicant will maintain, for 10 years, books, records, documents, and other evidence of accounting procedures and practices consistent with 42 CFR §423.505(d).		

B. If Applicant does not attest to being in compliance with the HIPAA security provisions as stated in 3.16A1, then complete and provide *Plan to Come into Compliance with HIPAA Security Requirements* (Appendix VI)

3.17 Claims Processing

A. Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:	**YES**	**NO**
1. Applicant develops and operates an on-line claims processing system that operates in real time to ensure accurate and timely payment of all claims submitted by network pharmacies on behalf of Part D plan enrollees. System operates according to the following standards: • 98% response within 4 seconds • 99% of all claims paid with no errors • 99% system availability *Note: In preparation for implementation CMS (except for scheduled down time and disasters) will conduct testing and otherwise monitor for the impact of TrOOP system interfaces with plan claims processing systems, and adjust these standards as appropriate if necessary.*		
2. Applicant develops and operates a paper claims processing system designed to pay claims submitted by non-network pharmacies on behalf of Part D plan enrollees. Applicant processes claims according to the following standards: • 100% of claims requiring no intervention handled within 15 calendar days • 100% of claims requiring intervention handled within 30 calendar days • 99% of all manually keyed claims paid with no errors		
3. If mail order pharmacy is offered, Applicant mail order processing meets three business day turnaround time from the point of receipt of prescription for in-stock items with no intervention to the point of shipment		
4. If mail order pharmacy is offered, Applicant mail order processing meets five business day turnaround time from the point of receipt of prescription for in-stock items with intervention to the point of shipment		
5. Applicant will develop and have available for CMS inspection a complete description of your claims adjudication system including: • Hardware and software • Operating system • MediSpan or First Data Bank database, including number of iterations saved • Number of sites processing claims (including disaster recovery back-up		

system) • System volume in covered lives, including the number of transactions the system can support per day and per hour.		
6. Applicant will develop and have available to CMS upon request policies and procedures that include a complete description and flow chart detailing the claims adjudication process for each: • Contracted network pharmacies • Out-of-network pharmacies • Paper claims • Batch-processed claims • Manual claim entry (e.g. for processing direct member reimbursement)		
7. Applicant will develop and will make available to CMS upon request policies and procedures that include a complete description of claim detail management, including: • The length of time that detailed claim information is maintained online (not less than 12 months) • The data storage process after it is no longer online • The length of time that detailed claim information is stored when it is no longer online (not less than 10 years)		
8. Applicant will develop and have available to CMS upon request policies and procedures that include a complete description of the accessibility of this information for data capture purposes and flow chart of the claims data retrieval process for each: • Entire claims history file • Encounter data required by state mandates • Encounter data required by alternate funding sources • Out-of-pocket maximum/deductible files		
9. Applicant will develop and have available to CMS upon request policies and procedures that include a description of how overpayments and underpayments to pharmacies, as well as enrollees, are handled and recovery procedures		
10. Applicant will develop and have available to CMS upon request policies and procedures that include a complete description of procedures surrounding disputed claims, including: • The steps that a pharmacy and/or enrollee must follow to dispute a claim reimbursement • The average amount of time needed to resolve a claims dispute • Turnaround time standards for dispute resolution.		
11. Applicant will have a robust testing process that will identify and correct any plan configuration errors prior to implementation.		
12. Applicant will accept eligibility files and any prior claims data electronically in NCPDP format.		
13. Applicant can and will document the manner and extent to which it has tested benefit designs such as drug exclusions or quantity limitations and plan parameters such as co-payments or benefit maximums.		

4.0 CERTIFICATION

I, the undersigned, certify to the following:

1) I have read the contents of the completed application and the information contained herein is true, correct, and complete. If I become aware that any information in this application is not true, correct, or complete, I agree to notify the Centers for Medicare & Medicaid Services (CMS) immediately and in writing.

2) I authorize CMS to verify the information contained herein. I agree to notify CMS in writing of any changes that may jeopardize my ability to meet the qualifications stated in this application prior to such change or within 30 days of the effective date of such change. I understand that such a change may result in termination of the approval.

3) I agree that if my organization meets the minimum qualifications and is Medicare-approved, and my organization enters into a Part D contract with CMS, I will abide by the requirements contained in Section 3.0 of this Application and provide the services outlined in my application.

4) I agree that CMS may inspect any and all information necessary including inspecting of the premises of the Applicant's organization or plan to ensure compliance with stated Federal requirements including specific provisions for which I have attested. I further agree to immediately notify CMS if despite these attestations I become aware of circumstances which preclude full compliance by January 1, 2006 with the requirement stated here in this application as well as in Part 423 of 42 CFR of the regulation.

5) I understand that in accordance with 18 U.S.C. § 1001, any omission, misrepresentation or falsification of any information contained in this application or contained in any communication supplying information to CMS to complete or clarify this application may be punishable by criminal, civil, or other administrative actions including revocation of approval, fines, and/or imprisonment under Federal law.

6) I further certify that I am an authorized representative, officer, chief executive officer, or general partner of the business organization that is applying for qualification to enter into a Part D contract with CMS.

_____	_____
Authorized Representative Name (printed)	Title
_____	_____
Authorized Representative Signature	Date (MM/DD/YYYY)

5.0 APPENDICES

Return Form to: MDCN@CMS.HHS.GOV
Subject: CMS Connectivity Request Form

APPENDIX I

CMS CONNECTIVITY REQUEST FORM
Prescription Drug Plan

THE FOLLOWING ORGANIZATION IS REQUESTING CONNECTIVITY TO CMS FOR THE PRESCRIPTION DRUG PLAN	
Name of Organization:	
Primary Contact Name:	Primary Contact Telephone Number:
Address *(Street, City, State, Zip)*:	
Telecommunications Contact Name:	
Telecommunications Contact Email:	
Physical Site Address (Must be the physical location for the T1 installation):	

1. Does your site have leased line IP connectivity into the MDCN (Medicare Data Communications Network) via AGNS (AT&T Global Network Services)? ☐ Yes. Please answer questions 2-13. ☐ No. Please answer questions 4-13.
2. What are the AGNS account names; i.e. BXKY, BXSC, CWF3, associated with the physical location to be used for drug card transactions? (For example, the AGNS account for the IP connectivity into the CMS central office is HCFA).
3. Are there other locations networked to the physical site? ☐ Yes ☐ No If yes please list the city and state below.
4. What are the IP networks/sub-network masks that will be communicating with CMS? (This is required for both ends of the connectivity so routing can be put in place over the new PVC built across the AGNS.) Please note you may need to contact your network administrator for this information *NOTE: If the AGNS router is placed on a ring/segment upstream from the origination network(s), CMS will need to know what the next hop will be out of the AGNS router to get to the cascaded network(s)*.
5. Do you currently have Connect: Direct that you will use for the Medicare Prescription Drug Program within your system infrastructure? ☐ Yes. Please answer question a below. ☐ No. Please answer questions b and c below.
a. Which version of Connect: Direct to you currently have within your infrastructure; i.e. enterprise, workstation (runs on PC) or satellite (LAN/Server based)?
b. Please provide the following information for Connect: Direct software installation on the hardware resident within your infrastructure. Make & Model of Hardware Where Software Will Reside: Number of Processors Associated with this Hardware: Operating System Used on the Hardware:
c. Who is the contact person(s) who will be responsible for the Connect: Direct Software? Name: Phone Number: Email Address:

6. For T1 installation, what type of LAN will connect to the CMS router; i.e. ethernet, token ring?
7. Will this new site require non-portable registered IP addresses from AGNS? ☐ Yes ☐ No. If yes, how many? If no, what addresses will be used at this site (sub-network/mask) and what IP address/sub-network mask should be used as the LAN interface address on the AGNS router?
8. What protocols will need to be enabled for this site; i.e. IP, SNA?
9. Will this site require the use of a dynamic routing protocol to advertise/learn routes to/from the AT&T Business Services network; i.e. IGRP, EIGRP, OSPF, BGP? ☐ Yes ☐ No If no, CMS will assume static routes should be used on the router placed at the new site.
10. What IP network(s) or host(s) at this site, including sub-network mask(s), will need to be able to communicate with what IP network(s) or host(s) at other sites and vice versa? Please include subnetwork masks for the destination network(s) as well *NOTE: If the AGNS router is placed on a ring/segment upstream from the origination network(s), CMS will need to know what the next hop will be out of the AGNS router to get to the cascaded network(s).*
11. Does this site have connectivity out to the Internet?
12. If there is connectivity out to the Internet, please describe the firewall used at the site for which this is applicable. Socks or proxy: Firewall software/hardware:
13. Is there any unsolicited inbound traffic permitted from the Internet through the firewall?
14. Will AGNS MDCN WAN be connected to the secure side of the firewall?
15. Are there any dial-up connectivity requirements to the sub-network(s) at this site?

Questions about completing the CMS Connectivity Request form should be sent to:
MDCN@CMS.HHS.GOV with Part D Benefit as the subject line.

APPENDIX II

Instructions for Accessing CMS Systems
Health Plan Management System (HPMS)

PDPs will be required to use HPMS to carry out various CMS Part D functions, including the application process, formulary submission process, bid submission process, ongoing operations of the Part D program, and reporting and oversight activities. PDPs will need the following to access HPMS:

(1) Internet **or** Medicare Data Communications Network (MDCN) connectivity,
(2) Use of a Microsoft Internet Explorer web browser (version 5.1 or higher) with 128-bit encryption, and
(3) A CMS-issued user ID and password with access rights to HPMS for each user within the PDP organization who will require such access.

Applicants should access the CMS website at http://www.cms.hhs.gov/mdcn/access.pdf to obtain the latest version of the "Application for Access to CMS Computer Systems" form. In addition to completing each section of the form, as appropriate, the PDP user should: 1) check **"Other"** in Section 2 and write **PDP** in the corresponding blank line, and 2) write **HPMS** on the first blank line in Section 3a.

In order to expedite the processing of this request, CMS strongly recommends that organizations refrain from requesting any additional systems access other than HPMS on this particular form submission at this time. When submitting this form during the notice of intent process, PDP applicants will not yet have received their pending PDP contract number (S number). As a result, applicants should leave Section 2h of the form blank during this initial submission period. Once a pending contract number has been assigned, all subsequent user ID request forms must include the applicant's contract number in Section 2h.

You must also sign and date page 2 containing the Privacy Act statement and return it along with the form. Your request cannot be processed without this signature and date. The original signed form (both pages) must be mailed to the following address:

Centers for Medicare & Medicaid Services
Attention: Marietta Mack
Mail Stop S1-05-06 / Location S2-04-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Please contact Don Freeburger (410-786-4586 or DFreeburger@cms.hhs.gov) or Greg Buglio (410-786-6562 or GBuglio@cms.hhs.gov) with any questions. CMS will provide you with additional technical instructions on accessing HPMS, including its website address, once your user ID has been processed.

Important Note for Current HPMS Users
If your organization already has HPMS access for other CMS functions, such as an MA organization or as a Drug Card Sponsor, you do not need to request new CMS user IDs, unless you need to do so to obtain HPMS access for new PDP users at your organization. Once your new PDP organization is assigned a pending contract number, you will be directed to provide CMS with the list of current user IDs that require access to the new PDP contract number in HPMS. CMS will provide all organizations with those instructions at the time of contract enumeration.

Other CMS Systems
Applicants will also be required to obtain access to other CMS systems in order to perform necessary operational functions, including, but not limited to, enrollment and claims submission. Instructions for obtaining access to those other systems will be provided to Applicants separately.

APPENDIX III

Banking Information Form

As Government vendors, organizations with Medicare contracts are paid by the Department of Treasury through an Electronic Funds Transfer (EFT) program. Government vendor payments are directly deposited into corporate accounts at financial institutions on the expected payment date. Additionally, CMS must have the EIN/TIN and associated name as registered with the IRS.

Please provide the following information to assist the Centers for Medicare and Medicaid Services in establishing payment arrangements for your organization.

ORGANIZATION INFORMATION

Name of Organization:	DBA, if any:
Full Address of Organization *(Street, City, Zip):*	
Contact Person Name:	Telephone Number:
Contract Numbers, if known:	
Employer/Tax Identification Number (EIN/TIN):	
EIN/TIN Name (*Name of Business for tax purposes as registered with the IRS):* *A W-9 may be required*	
Full Address for 1099 Tax Form *(Street, City, Zip)*:	

FINANCIAL INSTITUTION

Name of Bank:	
Full Address of Bank *(Street, City, Zip):*	
ACH/EFT Coordinator Name:	Telephone Number:
Nine Digit Routing Transit (ABA Number):	
Depositor Account Title:	
Depositor Account Number:	
Check Account Type: *(Please Attach a Copy of A Voided Check)* ☐Checking ☐Savings	

SIGNATURE & TITLE OF ORGANIZATION'S AUTHORIZED REPRESENTATIVE

Signature: _____

Date: _____

Title: _____

Print Name: _____

Phone Number: _____

APPENDIX IV

Application to Request Federal Waiver of State Licensure Requirement for Prescription Drug Plan (PDP)

A. COMPLETE THE TABLE BELOW

IDENTIFY THE CORPORATION SEEKING WAIVER OF STATE LICENSURE REQUIREMENT FOR PDP PLAN	
Full Legal Corporate Name:	D.B.A:
Full Address of Corporation: *(Street, City, State, Zip – No Post Office Boxes):*	
Corporation Telephone Number:	Corporation Fax Number:
PROVIDE THE CORPORATION'S CONTACT INFORMATION FOR THE PERSON WHO WILL ACT AS THE MAIN CONTACT	
Name of Individual:	Title:
Address of Individual: *(Street, City, State, Zip – No Post Office Boxes):*	
Direct Telephone Number:	Fax Number:
Email Address:	

B. REQUEST
I, on behalf of the legal entity identified in Section A, above, hereby request that the Secretary of the Department of Health and Human Services, pursuant to the authority granted under Section 1855(a) (2) and Section 1860D-12(c) of the Social Security Act, grant a waiver of the requirement that our organization be licensed under (Name of State or for Regional Plan Waiver, States) _____ State laws as a risk-bearing entity eligible to sponsor prescription drug benefits coverage.

D. CERTIFICATION
The undersigned officer has read this completed request for federal waiver form and does hereby declare that the facts, representations, and statements made in this form together with any attached information are true and complete to the best of my knowledge, information, and belief. The information herein declared by me represents matters about which I am competent, qualified, and authorized to represent the corporation. If any events, including the passage of time, should occur that materially change any of the answers to this request for federal waiver, the corporation agrees to notify the Centers for Medicare & Medicaid services immediately.

Corporate Name: _____
By: _____
Print Name: _____
Title: _____
Witness/Attest: _____

E. SUBMTTING FORM
If submitting separately from the Part D PDP or MA-PD application, send 3 copies of this waiver request form to the below address. Applicants must send no sooner than February 18, 2005 and no later than June 1, 2005.

Centers for Medicare & Medicaid Services (CMS)
Center for Beneficiary Choices
Attention: Marietta Mack
7500 Security Boulevard
Mail Stop S1-05-06/Location S2-04-05
Baltimore, Maryland 21244-1850

F. INSTRUCTIONS FOR COMPLETING COVER SHEET OF LICENSURE WAIVER APPLICATION

Section A

- Enter the corporate name
- Enter the name under which your PDP will do business (D.B.A)
- Enter the street address, telephone number and facsimile number of the Corporation at its corporate headquarters
- Enter the name, title, telephone number, fax number, and email address of the main contact person

Section B

- Indicate the State for which you are requesting a waiver or the States for which you are requesting a Regional Plan Waiver.

Section C

- Have a duly appointed corporate officer sign this form in the presence of a witness

If you have any questions regarding this form please contact:
Joseph Millstone
410-786-2976

(THIS SECTION FOR OFFICIAL USE ONLY)

Supporting Documentation for Request of Federal Waiver of State Licensure Requirement for Prescription Drug Plan (PDP) Sponsors

I. BACKGROUND AND PURPOSE

This waiver request form is for use by Applicants who wish to enter into a contract with the Centers for Medicare and Medicaid Services (CMS) to become Prescription Drug Plan (PDP) sponsors and provide prescription drug plan benefits to eligible Medicare beneficiaries without a State risk-bearing entity license.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) generally requires Applicants who wish to become PDP sponsors to be licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which the Applicant wishes to offer a PDP. However, the MMA created several exceptions to this State licensure requirement. These exceptions are similar to those applying to Provider Sponsored Organizations under the Balanced Budget Act of 1997.

In general, there are 2 types of waivers – both of which are more fully explained in Section II below. The waivers are: (1) Single State waivers. For these waivers, the Applicant should submit a separate waiver request for each State, and the waiver is effective only with respect to the single State. For applications submitted for plan years 2006 and 2007, special waivers are available as discussed more fully in Section II below. (2) Regional plan waivers. These waivers may be obtained if an Applicant is licensed in one State in a region and wishes to receive a waiver for all the other States in the region in which it is not licensed. In this case, the entity need only submit one waiver request – not one for each and every State in which it is not licensed.
Waiver requests should be submitted to CMS using the criteria described in the remainder of this paper.

Approval of a waiver request, in no way suggests that the Applicant is approved for a Medicare contract with CMS. Following approval of a waiver request, the Applicant will be required to submit a Medicare contract application that demonstrates that the Applicant can meet the Federal definition of a PDP sponsor and that the prescription drug plan being offered will meet all plan requirements for PDPs.

Applicants who receive a waiver from State licensure must also comply with CMS standards for financial solvency and capital adequacy if they wish to receive a PDP contract.

II. WAIVER ELIGIBILITY

The following constitute the waivers available to Applicants. These are the sole grounds for receiving waivers.

A. SINGLE STATE WAIVER

The Applicant is requesting a single state waiver for the following state: _____. Please indicate the grounds upon which you are requesting a waiver (check all applicable areas).

1. The State has failed to complete action on a licensing application within 90 days of the date of the State's receipt of a substantially complete application. 42 CFR 423. 410(b) (1).
2. The State does not have a licensing process in effect with respect to PDP sponsors. 42 CFR 423.410(c).

3. For applications for plan years 2006 and 2007 only, the Applicant has submitted a substantially complete licensure application to each State for which it requests a waiver. 42 CFR 423.410(d).
4. The State has denied the license application on the basis of one of the following: (a) material requirements, procedures, or standards (other than solvency requirements) not generally applied by the State to other entities engaged in a substantially similar business; or (b) the State requires, as a condition of licensure, the Applicant to offer any product or plan other than a PDP. 42 CFR 423.410(b)(2).
5. The State has denied the licensure application, in whole or in part, for one of the following reasons: (a) on the basis of the Applicant's failure to meet solvency requirements that are different from the solvency standards developed by CMS; or (b) the State has imposed, as a condition of licensing, any documentation or information requirements relating to solvency that are different from the information or documentation requirements in the solvency standards developed by CMS. 42 CFR 423.410(b)(3).
6. The State has denied the licensure application on the basis of grounds other than those required under Federal law. 42 CFR 423.410(b)(4).

B. REGIONAL PLAN WAIVERS

The Applicant is State-licensed in the State(s) of _____ and is applying for a regional plan waiver in the following region(s): _____ as provided under 42 CFR 423.415(a). The Applicant must demonstrate that it submitted a substantially complete licensure application in each State in the region for which it does not already have State licensure, except that no such application is necessary if CMS determines that the State does not have a licensing process for potential PDP sponsors.

III. WAIVER DURATION

A. SINGLE STATE WAIVER

The Single State waiver listed in II.A is effective for up to 36 months only and cannot be renewed unless CMS determines that the State in question does not have a licensing process in effect with respect to PDP sponsors. Thus, by the end of the three-year waiver period the PDP sponsor must be State-licensed if it wishes to continue as a PDP sponsor, unless CMS determines that the State in question has chosen not to create a licensing process for PDP sponsors – in which case the waiver can continue until CMS determines that a licensure process has been created. The special waivers for 2006 and 2007 will not be available for Applications submitted for 2008 and thereafter. Single State waivers automatically terminate if the PDP sponsor obtains State licensure.

B. REGIONAL PLAN WAIVERS

The Regional Plan waivers expire at the end of the time period the Secretary determines is appropriate for timely processing of the licensure application, but in no case will a waiver extend beyond the end of the calendar year. For both Single State and Regional Plan waivers, the waiver will terminate if the contract with Medicare terminates.

IV. INFORMATION TO BE INCLUDED IN THIS REQUEST

While the applicant should provide information concerning each of the following areas, the specific information and documentation requested below are not necessarily all inclusive for CMS to approve or deny the request. Applicants should provide any information and all documentation necessary to substantiate their request.

a) Provide a written summary of the PDP entity or, if a line of business, a description of the entire organization. Also include information about management structure and the health care provider or group of affiliated health care providers that control the PDP. Discuss legal history, predecessor corporations, recent mergers or re-organizations, recent change-of-ownerships; any State licenses held, any previous or current contractual involvement with the Medicare program either directly with CMS or by contract with an HMO.

b) Provide a narrative of the circumstances leading to the PDP's eligibility for a waiver based on one of the grounds listed in section II. Include information about the State risk-bearing entity license for which the PDP applied, the application process that the PDP followed, and any relevant interaction with the State.

c) Provide documentation to substantiate the narrative required in (b). Depending on the grounds for waiver eligibility, this documentation should include but is not necessarily limited to the list below. For Regional Plan Waivers, group response to numbers 1-6, as they apply, by state:

1. Evidence of State's failure to act on a licensure application on a timely basis

Copy of the dated cover sheet to the application submitted to the State, State confirmation of the receipt and completeness of the application, State requests for additional information, and all pertinent correspondence with the State relating to the status of the application, etc.

2. Evidence that Applicant submitted licensure application to the State (special 2006/2007 waiver)

Copy of cover letter to appropriate State authority that accompanied Applicant's licensure application.

3. Evidence of denial of the application based on discriminatory treatment

Copy of denial letter from the State, copy of "discriminatory" material requirements (including, State laws and regulation), procedures or standards to which the PDP was required to comply that are not generally applicable to other entities engaged in a substantially similar business, a copy of State licensure requirements that the PDP offer a particular product or plan in addition to a Medicare Advantage plan, and any supplemental material received from the State explaining their rationale for the denial, etc.

PDPs seeking a waiver on the grounds that they are subject to requirements, procedures and standards not applicable to entities engaged in a "substantially similar business" must demonstrate through submission of these and other appropriate materials:

a) The types of entities subject to the different requirements, procedures and standards are engaged in a "substantially similar business".

b) The State requirements, procedures and standards imposed on the PDP entity are not applicable to other "substantially similar business" entities.

4. Evidence of denial of the application based on solvency requirements
Copy of denial letter from the State, copy of State solvency requirements, demonstration of the difference between State solvency requirements, procedures and standards and Federal PDP solvency requirements, procedures and standards, any other State information regarding documentation, information, and other material requirements, procedures or standards relating to solvency, or any correspondence detailing the reason the application was denied, etc.

5. Evidence of State licensure standards other than those required by Federal law
Memo identifying the State licensure standards by reference to relevant State law, regulation, or policy guidance and describing the how those standards differ from those required by Federal law.

6. Regional Plan Waiver
Evidence of licensure in one State within a regional plan and evidence that a substantially complete application has been submitted to the other States in the region – unless CMS determines that there is no PDP licensing process in effect in a State.

d) Provide the name, address and telephone number of all State regulatory officials involved in the State application and/or denial proceedings.

e) Please cite and describe any current PDP laws and/or legislation in the State.

f) Briefly describe the proposed service area including counties and major cities. It is not necessary at this time to include maps. Note: if the organization plans on providing services in more than one State where it is not licensed, it will have to file a separate waiver request for each State.

g) Provide any other information that you believe supports your request for a waiver under Section II.

V. OVERVIEW OF WAIVER REQUEST PROCESS

For single-state waivers, section 1860D-12(c) and section 1855(a)(2) of the Act requires the Secretary to grant or deny this waiver request within 60 days after the date the Secretary determines that a substantially complete application has been filed. Upon receipt of a waiver request, CMS will review it to determine whether it contains sufficient information to approve or deny the request. The 60-day review period begins at the time CMS determines that the applications is substantially complete. For those applications deemed incomplete, CMS will work with the applicant to identify the remaining information necessary to either approve or deny the request.

APPENDIX V

HIPAA Security Attestation Statement

(Date)

_____ (MA-PDP, PDP etc.) attests that, as of the initial enrollment date, appropriate administrative, technical and physical safeguards will be in place to protect the privacy of protected health information in accordance with 45 CFR §164.530(c), and that we will meet the standards, requirements and implementation specifications as set forth in 45 CFR part 164, subpart C, the HIPAA Security Rule, prior to beginning enrollment of beneficiaries.

_____

(Signature of Chief Information Officer)

APPENDIX VI

Plan to Come into Compliance with HIPAA Security Requirements

Modified from HIPAA Security Rule Appendix A to Subpart C to Part 164[3] -- Security Standards: Matrix

Complete the tables below using this example:

Standards	Sections	Implementation Specifications (R)=Required, (A)= Addressable		Project / Activity	Scheduled Completion
Security Awareness and Training	164.308(a)(5)	Security Reminders	(A)	Perform gap analysis, develop awareness program	3Q CY 2005
		Protection from Malicious Software	(A)		
		Log-in Monitoring	(A)		
		Password Management	(A)		

ADMINISTRATIVE SAFEGUARDS (see § 164.308)

Standards	Sections	Implementation Specifications (R)=Required, (A)= Addressable		Project/Activity	Scheduled Completion
Security Management Process	164.308(a)(1)	Risk Analysis	(R)		
		Risk Management	(R)		
		Sanction Policy	(R)		
		Information System Activity Review	(R)		
Assigned Security Responsibility	164.308(a)(2)		(R)		
Workforce Security	164.308(a)(3)	Authorization and/or Supervision	(A)		
		Workforce Clearance Procedure	(A)		
		Termination Procedures	(A)		
Information Access Management	164.308(a)(4)	Isolating Health Care Clearinghouse Function	(R)		
		Access Authorization	(A)		
		Access Establishment and Modification	(A)		
Security Awareness and Training	164.308(a)(5)	Security Reminders	(A)		
		Protection from Malicious Software	(A)		
		Log-in Monitoring	(A)		
		Password Management	(A)		

[3] 45 CFR parts 160, 162 and 164 Health Insurance Reform: Security Standards; Final Rule

Security Incident Procedures	164.308(a)(6)	Response and Reporting	(R)		
Contingency Plan	164.308(a)(7)	Data Backup Plan	(R)		
		Disaster Recovery Plan	(R)		
		Emergency Mode Operation Plan	(R)		
		Testing and Revision Procedure	(A)		
		Application and Data Criticality Analysis	(A)		
Evaluation	164.308(a)(8)		(R)		
Business Associate Contracts and other Arrangement	164.308(b)(1)	Written Contract or Other Arrangement	(R)		

PHYSICAL SAFEGUARDS (see § 164.310)

Standards	Sections	Implementation Specifications (R)=Required, (A)= Addressable		Project	Scheduled Completion
Facility Access Controls	164.310(a)(1)	Contingency Operations	(A)		
		Facility Security Plan	(A)		
		Access Control and Validation Procedures	(A)		
		Maintenance Records	(A)		
Workstation Use	164.310(b)		(R)		
Workstation Security	164.310(c)		(R)		
Device and Media Controls	164.310(d)(1)	Disposal	(R)		
		Media Re-use	(R)		
		Accountability	(A)		
		Data Backup and Storage	(A)		

TECHNICAL SAFEGUARDS (see 164.312)

Standards	Sections	Implementation Specifications (R)=Required, (A)=Addressable		Project	Scheduled Completion
Access Control	164.312(a)(1)	Unique User Identification	(R)		
		Emergency Access Procedure	(R)		
		Automatic Logoff	(A)		
		Encryption and Decryption	(A)		
Audit Controls	164.312(b)		(R)		
Integrity	164.312(c)(1)	Mechanism to Authenticate Electronic Protected Health Information	(A)		
Person or Entity Authentication	164.312(d)		(R)		
Transmission Security	164.312(e)(1)	Integrity Controls	(A)		
		Encryption	(A)		

APPENDIX VII

Pharmacy Access Standards

§ 423.120 Access to Covered Part D Drugs

(a) Assuring pharmacy access.

(1) Standards for convenient access to network pharmacies. Except as provided in paragraph (a) (7) of this section, a Part D plan must have a contracted pharmacy network, consisting of retail pharmacies sufficient to ensure that for beneficiaries residing in each State in the prescription drug plan's service area, (as defined in § 423.112 (a)), each State in a regional MA-PD plan's service area, (as defined in § 422.2 and § 422.455 (a) of this chapter), a local MA-PD plan's service area (as defined in § 422.2 of this chapter), or a cost plan's geographic area (as defined in § 417.401 of this chapter), the following requirements are satisfied:

(i) At least 90 percent of Medicare beneficiaries, on average, in urban areas served by the Part D plan live within 2 miles of a network pharmacy that is a retail pharmacy or a pharmacy described under paragraph (a) (2) of this section;

(ii) At least 90 percent of Medicare beneficiaries, on average, in suburban areas served by the Part D plan live within 5 miles of a network pharmacy that is a retail pharmacy or a pharmacy described under paragraph (a) (2) of this section; and

(iii) At least 70 percent of Medicare beneficiaries, on average, in rural areas served by the Part D plan live within 15 miles of a network pharmacy that is a retail pharmacy or a pharmacy described under paragraph (a) (2) of this section.

(2) Applicability of some non-retail pharmacies to standards for convenient access. Part D plans may count I/T/U pharmacies and pharmacies operated by Federally Qualified Health Centers and Rural Health Centers toward the standards for convenient access to network pharmacies in paragraph (a) (1) of this section.

Email Form to: drugbenefitimpl@cms.hhs.gov
Subject: Notice of Intent to Apply

APPENDIX VIII

Notice of Intent to Apply

Complete this form to indicate your intent to apply.

Applicant Organization's Legal Entity Name:

Applicant Organization's Corporate Address *(Street, City, State, Zip – No Post Office Boxes):*

Type of Medicare Prescription Drug Benefit Contract Request: ☐ PDP ☐ MA-PD

If PDP Sponsor, Type of Risk Anticipated: ☐ Full Risk ☐ Partial Risk ☐ Both

If MA-PD, type of product represented by this notice. *Note: Select only one and provide a different notice for each product type to be offered by the Applicant entity*: ☐ HMO ☐ HMO POS ☐ PSO ☐ PFFS ☐ Regional PPO

PROVIDE THE INFORMATION BELOW REGARDING YOUR PHARMACY BENEFITS	
Pharmacy Benefit Management Organization's Full Name. *Note: If Applicant contracts with multiple Pharmacy Benefit Management Organizations, be sure to list all:*	
Does the Applicant anticipate submitting a formulary? *Note: CMS is using this information to understand how many formularies it may need to review beginning April 18, 2005.* ☐ Yes ☐ No	
If yes, indicate how many formularies you anticipate to submit: If no, indicate if all drugs will have the same cost-sharing: ☐ Yes ☐ No	
PROVIDE THE INFORMATION BELOW FOR THE PERSON WHO WILL ACT AS THE MAIN CONTACT	
Name of Individual:	Title:
Address of Individual: *(Street, City, State, Zip – No Post Office Boxes):*	
Direct Telephone Number:	Fax Number:
Email Address:	
IDENTIFY THE REGION APPLICANT INTENDS TO SERVE: *Note: MA & PDP region number information may be found at the following website: www.cms.hhs.gov/medicarereform/mmaregions/pdpmaosum.asp*	
If PDP Sponsor, identify PDP regions to be served using region numbers:	If MA-PD Sponsor offering regional PPO, identify MA regions to be served using region numbers:
If MA-PD Sponsor offering local plan, identify state, county, and zip code:	
PROVIDE THE INFORMATION BELOW ON LICENSURE	
Are you licensed (or is your application pending at the state) to be a risk-bearing entity in any state in which you propose to offer Part D drug benefits? ☐ Yes ☐ No If yes, please complete the table below. Add additional rows as necessary.	

List State(s) in which you Already Possess or Have Applied for License	**Status of License** *Indicate the status using an "x" to mark the appropriate column*		**Dates of License** *Complete either Effective and Expiration Dates or Submission Date*		
	Licensed	License Application Submitted	Effective Date	Expiration Date	Submission Date

PROVIDE THE INFORMATION BELOW ON STATE LICENSURE REQUIREMENT WAIVERS. ADD ADDITIONAL ROWS AS NECESSARY.		
List the State(s) for Which a Licensure Requirement Waiver has Been or will be Requested	**Status of License Requirement Waiver** *Use the key below to indicate your response.* X = Waiver application is to be submitted. Provide anticipated date of submission. A = Waiver application submitted and approved. Provide date approved. P = Waiver application submitted and pending. Provide date submitted. D = Waiver application denied. Provide date denied.	
	Status	Date

Note: This Notice of Intent to Apply must be emailed to drugbenefitimpl@cms.hhs.gov by 5:00 p.m. EST on February 18, 2005. Be sure to indicate "NOTICE OF INTENT" in the subject line.

APPENDIX IX

CERTIFICATION OF MONTHLY ENROLLMENT AND PAYMENT DATA RELATING TO CMS PAYMENT TO A PDP

Pursuant to the contract(s) between the Centers for Medicare and Medicaid Services (CMS), and _____ *(name of PDP)* hereafter referred to as the "Prescription Drug Plan" governing the operation of the following PDPs _____ *(plan identification numbers)*, the PDP hereby requests payment under the contract, and in doing so, makes the following certifications concerning CMS payments to the PDP. The PDP acknowledges that the information described below directly affects the calculation of CMS payments to the PDP and that misrepresentations to CMS about the accuracy of such information may result in Federal civil action and/or criminal prosecution. This certification shall not be considered a waiver of the PDP's right to seek payment adjustments from CMS based on information or data that does not become available until after the date the PDP submits this certification.

1. The PDP has reported to CMS for applications received in the month of_____ *(month and year)* all new enrollments, disenrollments, and changes in Plan Benefit Packages with respect to the above-stated PDPs. Based on best knowledge, information, and belief, all information submitted to CMS in this report is accurate, complete, and truthful.

2. The PDP has reviewed the CMS monthly membership report and reply listing for the month of _____ *(month and year)* for the above-stated PDPs and has submitted requests to the IntegriGuard, under separate cover, for retroactive adjustments to correct payment data when the PDP has more accurate information. This may include enrollment status and State and County Code related to specific beneficiary. For those portions of the monthly membership report and the reply listing to which the PDP raises no objection, the PDP, through the certifying CEO/CFO,
will be deemed to have attested, based on best knowledge, information, and belief, to their accuracy, completeness, and truthfulness.

NAME: _____
TITLE: _____
On behalf of: _____ *(PDP)*

NOTE: The person signing this form must be the CEO, CFO, or an individual delegated the authority to sign on behalf of on of the CEO or CFO and who reports to the CEO or CFO. Otherwise the certification will be considered invalid, per CFR 423.505 (k).

APPENDIX X

Financial Solvency Documentation
For Applicant Not Licensed as a Risk-bearing Entity in Any State

I. DOCUMENTATION

A. Net Worth - Minimum Net Worth: $1.5 million

1. Documentation of Minimum Net Worth

At the time of application, the potential PDP Sponsor not licensed in any state must show evidence of the required minimum net worth. The PDP Sponsor must demonstrate this through an independently audited financial statement if it has been in operation at least twelve months.

If the organization has not been in operation at least twelve months it may choose to 1) obtain an independently audited financial statement for a shorter time period; or 2) demonstrate that it has the minimum net worth through presentation of an unaudited financial statement that contains sufficient detail that CMS may verify the validity of the financial presentation. The unaudited financial statement must be accompanied by an actuarial opinion by a qualified actuary regarding the assumptions and methods used in determining loss reserves, actuarial liabilities and related items.

A qualified actuary for the purposes of this application means a member in good standing of the American Academy of Actuaries or a person recognized by the Academy as qualified for membership, or a person who has otherwise demonstrated competency in the field of actuarial determination and is satisfactory to CMS.

B. Financial Plan

1. Plan Content and Coverage

At the time of application, the PDP Sponsor must submit a business plan (with supporting financial projections and assumptions, satisfactory to CMS), covering the first twelve months of operation under the Medicare contract and meeting the requirements stated below. If the plan projects losses, the business plan must cover the period for twelve months past the date of projected break-even.

The business plan must include a financial plan with:

a. A detailed marketing plan;
b. Statements of revenue and expense on an accrual basis;
c. A cash flow statement;
d. Balance sheets;
e. The assumptions in support of the financial plan;
f. If applicable, availability of financial resources to meet projected losses; and
g. Independent actuarial certification of business plan assumptions and plan feasibility by a qualified actuary.

2. Funding for Projected Losses

(a) Allowable sources of funding:

In the financial plan, the PDP Sponsor must demonstrate that it has the resources available to meet the projected losses for time-period to breakeven. Except for the use of guarantees as provided in

section (a) below, letters of credit as provided in section (b) below, and other means as provided in section (c) below, the resources must be assets on the balance sheet of the PDP Sponsor in a form that is either cash or is convertible to cash in a timely manner (i.e. current assets), pursuant to the financial plan.

(i) Guarantees will be acceptable as a resource to meet projected losses under the conditions detailed in Section III, Guarantees.

(ii) An irrevocable, clean, unconditional, evergreen letter of credit may be used in place of cash or cash equivalents if prior approval is obtained from CMS. It must be issued or confirmed by a qualified United States financial institution as defined in Section II.B, Insolvency, below. The letter of credit shall contain an issue date and expiration date and shall stipulate that the beneficiary need only draw a sight draft under the letter of credit and present it to obtain funds and that no other document need be presented.

"Beneficiary" means the PDP sponsor for whose benefit the credit has been established and any successor of the PDP sponsor by operation of law. If a court of law appoints a successor in interest to the named beneficiary, then the named beneficiary includes the court appointed bankruptcy trustee or receiver.
The letter of credit also shall indicate that it is not subject to any condition or qualifications any other agreement, documents or entities.

CMS must be notified in writing thirty days prior to the expiration without renewal or the reduction of a proposed or existing letter of credit or replacement of a letter of credit by one for a reduced amount.

Prior written approval of CMS should be secured by the PDP sponsor of any form of proposed letter of credit arrangements before it is concluded for purposes of funding for projected losses.

(iii) If approved by CMS, based on appropriate standards promulgated by CMS, a PDP sponsor may use the following to fund projected fund losses for periods after the first year: lines of credit from regulated financial institutions, legally binding agreements for capital contributions, or other legally binding contracts of a similar level of reliability.

NOTE: A plan needs to maintain its $1.5 million in net worth to meet the net worth standard (Section A, above) and may not use any portion of this net worth amount to fund the projected losses. Net worth in excess of $1.5 million, which is funded through the forms allowable for meeting projected losses (i.e., cash, cash equivalents, etc.,) may be counted in the projected losses funding however the minimum $750,000 liquidity requirement (Section C, below) must still be met and may not be used to meet the projected losses.

(b) Calculation of projected losses:

An applicant that has had state licensure waived must demonstrate that in order to cover projected losses, the applicant possesses allowable sources of funding sufficient to cover the greater of:

(i) 7.5 percent of the aggregated projected target amount for a given year (aggregated projected target amount is calculated by estimating the average monthly per capita cost of

benefits (excluding administrative costs) and multiplying that amount by member months for a 12 month period), or

(ii) Resources to cover 100% of any projected losses, if the business plan projects losses greater than 7.5% of the aggregated projected target amount.

The applicant must include with the application, a worksheet calculating the aggregated projected target amount as defined above.

C. Liquidity

The PDP Sponsor must have sufficient cash flow to meet its financial obligations as they become due. The amount of minimum net worth requirement to be met by cash or cash equivalents is $750,000. Cash equivalents are those that meet the definition of current assets that can be converted to cash in one year or less.

In determining the ability of a PDP Sponsor to meet this requirement, CMS will consider the following:

(a) The timeliness of payment,
(b) The extent to which the current ratio is maintained at 1:1 or greater, or whether there is a change in the current ratio over a period of time, and
(c) The availability of outside financial resources.

CMS may apply the following corresponding corrective action remedies:

(a) If the PDP Sponsor fails to pay obligations as they become due, CMS will require the PDP Sponsor to initiate corrective action to pay all overdue obligations.
(b) CMS may require the PDP Sponsor to initiate corrective action if any of the following are evident:
(1) the current ratio declines significantly; or
(2) a continued downward trend in the current ratio. The corrective action may include a change in the distribution of assets, a reduction of liabilities or alternative arrangements to secure additional funding to restore the current ratio to at least 1:1.
(c) If there is a change in the availability of the outside resources, CMS will require the PDP Sponsor to obtain funding from alternative financial resources.

D. Methods of Accounting

The PDP Sponsor may use the standards of Generally Accepted Accounting Principles (GAAP) or it may use the standards of Statutory Accounting Principles (SAP) applicable to the type of organization it would have been licensed as at the state level if a waiver were not granted by CMS. Whether GAAP or SAP is utilized however, there are certain additional differences cited below for waivered PDP Sponsors.

Generally Accepted Accounting Principles (GAAP) are those accounting principles or practices prescribed or permitted by the Financial Accounting Standards Board.
Statutory Accounting Principles are those accounting principles or practices prescribed or permitted by the domiciliary State insurance department in the State that the PDP Sponsor operates.

Waivered organizations should note that the maximum period of waiver is limited by Federal regulation. At such time as the waiver expires, the PDP Sponsor would have to obtain a risk bearing license.

Waivered PDP Sponsors should adjust their balance sheets as follows:

1. Calculation-Assets

   The following asset classes will not be admitted as assets:

   - Good will
   - Acquisition costs
   - Other similar intangible assets

2. Calculation- Liabilities

   Net worth means the excess of total admitted assets over total liabilities, but the liabilities shall not include fully subordinated debt.

   Subordinated debt means an obligation that is owed by an organization, that the creditor of the obligation, by law, agreement, or otherwise, has a lower repayment rank in the hierarchy of creditors than another creditor. The creditor would be entitled to repayment only after all higher ranking creditor's claims have been satisfied. A debt is fully subordinated if it has a lower repayment rank than all other classes of creditors and is payable out of net worth in excess of that required under Section IA, Net Worth and under Section IC, Liquidity above.

   In order to be considered fully subordinated debt for the purpose of calculating net worth, the subordinated debt obligation must be a written instrument and include:

   a) The effective date, amount, interest and parties involved.
   b) The principal sum and/or any interest accrued thereon that are subject to and subordinate to all other liabilities of the PDP sponsor, and upon dissolution or liquidation, no payment of any kind shall be made until all other liabilities of the PDP sponsor have been paid.
   c) The instrument states that the parties agree that the PDP sponsor must obtain written approval from CMS prior to the payment of interest or repayment of principal.

E. Financial Indicators and Reporting

The PDP Sponsor must file a Health Blank Form (in the same format as utilized by the National Association of Insurance Commissioners) to CMS. The portion of the Health Blank Form submitted to CMS will be limited to the following pages:

- Jurat Page
- Assets
- Liabilities, Capital and Surplus
- Statement of Revenue and Expenses
- Capital and Surplus Account
- Cash Flow
- Actuarial Opinion (the actuarial opinion is required only of annual report filings). In addition, the PDP Sponsor shall submit an annual independently audited financial statement with management letter.

Note: Future frequency of reporting will be both quarterly (first, second, and third quarters only) and annually to CMS. CMS may choose to initiate monthly reporting from certain PDP Sponsors who because of their financial status CMS deems may require additional monitoring.

Reporting shall be on the following schedule:

Quarterly reporting PDP sponsors shall report within 45 days of the close of a calendar quarter ending on the last day of March, June and September. No separate quarterly report shall be required for the final quarter of the year.

Annually reporting and quarterly reporting PDP sponsors shall report annually within 120 days of the close of the calendar year i.e. by April 30th or within 10 days of the receipt of the annual audited financial statement, whichever is earlier.

Financial reporting may be the under the principles of General Accepted Accounting Principles (GAAP) or under Statutory Accounting Principles (SAP) applicable to similar organizations of similar type within the state where the organization is based. However, if an organization chooses to report under GAAP, it may not report under GAAP for a period longer than 36 months unless a state has chosen to not license such organizations.

II. INSOLVENCY

A. Hold Harmless and Continuation of Coverage/Benefits

PDP Sponsors shall be subject to the same hold harmless and continuation of coverage/benefit requirements as other Medicare Advantage contractors.

B. Insolvency Deposit

$100,000 held in accordance with CMS requirements by a qualified U. S. Financial Institution. A qualified financial institution means an institution that:

1. Is organized or (in the case of a U. S. office of a foreign banking organization) licensed, under the laws of the United States or any state thereof; and
2. Is regulated, supervised and examined by U. S. Federal or State authorities having regulatory authority over banks and trust companies.

III. GUARANTEES

A. General policy.

A PDP Sponsor, or the legal entity of which the PDP Sponsor is a Component, may apply to CMS to use the financial resources of a Guarantor for the purpose of meeting the requirements of a PDP Sponsor. CMS has the discretion to approve or deny approval of the use of a Guarantor.

B. Request to use a Guarantor.

To apply to use the financial resources of a Guarantor, a PDP Sponsor must submit to CMS:

1. Documentation that the Guarantor meets the requirements for a Guarantor under paragraph (C) of this section; and
2. The Guarantor's independently audited financial statements for the current year-to-date and for the two most recent fiscal years. The financial statements must include the Guarantor's balance sheets, profit and loss statements, and cash flow statements.

C. Requirements for Guarantor.

To serve as a Guarantor, an organization must meet the following requirements:

1. Be a legal entity authorized to conduct business within a State of the United States.
2. Not be under Federal or State bankruptcy or rehabilitation proceedings.

3. Have an adjusted net worth (not including other guarantees, intangibles and restricted reserves) equal to three times the amount of the PDP Sponsor guarantee.
4. If a State insurance commissioner regulates the Guarantor, or other State official with authority for risk-bearing entities, it must meet the adjusted net worth requirement in this document with all guarantees and all investments in and loans to organizations covered by guarantees excluded from its assets.
5. If the Guarantor is not regulated by a State insurance commissioner, or other similar State official it must meet the adjusted net worth requirement in this document with all guarantees and all investments in and loans to organizations covered by a guarantee and to related parties (subsidiaries and affiliates) excluded from its assets and determination of adjusted net worth.

D. Guarantee document.

If the guarantee request is approved, a PDP Sponsor must submit to CMS a written guarantee document signed by an appropriate Guarantor. The guarantee document must:

1. State the financial obligation covered by the guarantee;
2. Agree to:
    a. Unconditionally fulfill the financial obligation covered by the guarantee; and
    b. Not subordinate the guarantee to any other claim on the resources of the Guarantor;
3. Declare that the Guarantor must act on a timely basis, in any case not more than 5 business days, to satisfy the financial obligation covered by the guarantee; and
4. Meet other conditions as CMS may establish from time to time.

E. Reporting requirement.

A PDP Sponsor must submit to CMS the current internal financial statements and annual audited financial statements of the Guarantor according to the schedule, manner, and form that CMS requests.

F. Modification, substitution, and termination of a guarantee.

A PDP Sponsor cannot modify, substitute or terminate a guarantee unless the PDP Sponsor:

1. Requests CMS's approval at least 90 days before the proposed effective date of the modification, substitution, or termination;
2. Demonstrates to CMS's satisfaction that the modification, substitution, or termination will not result in insolvency of the PDP Sponsor; and
3. Demonstrates how the PDP Sponsor will meet the requirements of this section.

G. Nullification.

If at any time the Guarantor or the guarantee ceases to meet the requirements of this section, CMS will notify the PDP Sponsor that it ceases to recognize the guarantee document. In the event of this nullification, a PDP Sponsor must:

1. Meet the applicable requirements of this section within 15 business days; and
2. If required by CMS, meet a portion of the applicable requirements in less than the time period granted in paragraph (G.1.) of this section.

APPENDIX XI

CERTIFICATION THAT SUBCONTRACTS MEET THE REQUIREMENTS OF SECTION 3.1.1F

A. I, the undersigned, certify, on behalf of LEGAL NAME, to the following:

The contracts submitted as attachments to Section 3.1.1:

1. Clearly identify the parties to the contract (or letter of agreement);
2. Describe the functions to be performed by the subcontractor, as well as any reporting requirements the subcontractor has to the Applicant identified in Section 3.1.1B of the application;
3. Contain language clearly indicating that the subcontractor has agreed to participate in your Medicare Prescription Drug Benefit program (except for a network pharmacy if the existing contract would allow participation in this program), and flow-down clauses requiring their activities be consistent and comply with the Applicant's contractual obligations as a PDP sponsor;
4. Contain language describing the services to be performed in a manner that encompasses the services required to support the Medicare Prescription Drug Benefit program;
5. Describe the payment the subcontractor will receive for performance under the contract, if applicable;
6. Are for a term of at least the first year of the program (i.e., January 1, 2006 through December 31, 2006);
7. Are signed by a representative of each party with legal authority to bind the entity;
8. Contain language obligating the subcontractor to abide by all applicable Federal and State laws and regulations and CMS instructions;
9. Contain language obligating the subcontractor to abide by State and Federal privacy and security requirements, including the confidentiality and security provisions stated in the regulations for the program at 42 CFR §423.136;
10. Contain language ensuring that the subcontractor will make their books and other records available in accordance with 42 CFR §423.505(i)(2), which generally states these regulations give HHS, the Comptroller General, or their designees the right to inspect, evaluate and audit books and other records and that these rights continue for a period of 10 years from the final date of the contract period or the date of audit completion, whichever is later;
11. Contain language stating that the subcontractor will ensure that beneficiaries are not held liable for fees that are the responsibility of the Applicant;
12. Contain language stating that if the Applicant, upon becoming a Part D sponsor, delegates an activity or responsibility to the subcontractor, that such activity or responsibility may be revoked if CMS or the Part D sponsor determines the subcontractor has not performed satisfactorily. The subcontract may include remedies in lieu of revocation to address this requirement;
13. Contain language specifying that the Applicant, upon becoming a Part D sponsor, will monitor the performance of the subcontractor on an ongoing basis; and
14. Contain language that the Part D sponsor retains the right to approve, suspend, or terminate any arrangement with a pharmacy if the subcontractor will establish the pharmacy network or select pharmacies to be included in the network.

B. I certify that I am authorized to sign on behalf of the Applicant.

C. I understand that CMS will review the submitted contracts to ensure that they comply with the contracting requirements stated in Section 3.1.1F of the Solicitation for Applications from Prescription Drug Plans (PDPs)/Medicare Advantage Prescription Drug Plan Sponsors/Cost Plan Sponsors. When a submitted contract does not meet a requirement, CMS will ask the Applicant to resubmit the contract in question. I understand the Applicant's failure to provide in a timely manner fully executed contracts that meet CMS requirements may affect CMS' decision to allow the Applicant to accept enrollment into its Part D plan(s) on November 15, 2005.

_____ _____

Authorized Representative Name (printed) Title

_____ _____

Authorized Representative Signature Date (MM/DD/YYYY

Appendix XII
Citations of Section 3.1.1 F Requirements in Subcontracts submitted as Attachments to Section 3.1.1

INSTRUCTIONS: Applicants must complete the following chart for each subcontractor submitted under Section 3.1.1F.

Applicants must identify where in each contract the following elements may be found.

Section	Requirement	Citation
3.1.1F1	The parties to the contract	
3.1.1F2	The functions to be performed by the subcontractor, as well as any reporting requirements the subcontractor has to the Applicant identified in Section 3.1.1B of the application.	
3.1.1F3	Language clearly indicating that the subcontractor has agreed to participate in your Medicare Prescription Drug Benefit program (except for a network pharmacy if the existing contract would allow participation in this program), and flow-down clause.	
3.1.1F4	Language describing the services to be performed in a manner that encompasses the services required to support the Medicare Prescription Drug Benefit program.	
3.1.1F5	The payment the subcontractor will receive for performance under the contract, if applicable.	
3.1.1F6	Are for a term of at least the first year of the program.	
3.1.1F7	Are signed by a representative of each party with legal authority to bind the entity.	
3.1.1F8	Language obligating the subcontractor to abide by all applicable Federal and State laws and regulations and CMS instructions.	
3.1.1F9	Language obligating the subcontractor to abide by State and Federal privacy and security requirements, including the confidentiality and security provisions stated in the regulations for the program at 42 CFR §423.136.	
3.1.1F10	Language ensuring that the subcontractor will make their books and other records available in accordance with 42 CFR §423.505(i)(2), which generally states these regulations give HHS, the Comptroller General, or their designees the right to inspect.	
3.1.1F11	Language stating that the subcontractor will ensure that beneficiaries are not held liable for fees that are the responsibility of the Applicant.	
3.1.1F12	Language stating that if the Applicant, upon becoming a Part D sponsor, delegates an activity or responsibility to the subcontractor, that such activity or responsibility may be revoked if CMS or the Part D sponsor determines the subcontractor has not performed satisfactorily. The subcontract may include remedies in lieu of revocation to address this requirement.	
3.1.1F13	Language specifying that the Applicant, upon becoming a Part D sponsor, will monitor the performance of the subcontractor on an ongoing basis.	

3.1.1F14	Language that the Part D sponsor retains the right to approve, suspend, or terminate any arrangement with a pharmacy if the subcontractor will establish the pharmacy network or select pharmacies to be included in the network.	

APPENDIX XIII
Citations for Pharmacy Access Contracts

INSTRUCTIONS: Applicants must complete the following chart (which contains applicable Section 3.1.1 F requirements AND additional requirements specific to Pharmacy Access, Long-Term Care and I/T/U contracts) for each pharmacy contract submitted under Section 3.4. Applicants must identify where in each contract the following elements reside.

Indicate the type of pharmacy to which contract applies:

□ Retail □ Mail Order □ Home Infusion □ Long-Term Care □ I/T/U (for IHS contracting)
□ I/T/U (for tribal contracting)

The provisions listed below must be in all pharmacy contracts. If contracts reference policies and procedures to which the pharmacy must abide, provide the relevant documentation as evidence and cite this documentation accordingly.

Section	Requirement	Citation
3.1.1F2	The functions to be performed by the subcontractor, as well as any reporting requirements the subcontractor has to the Applicant identified in Section 3.1.1B of the application.	
3.1.1F4	Language describing the services to be performed in a manner that encompasses the services required to support the Medicare Prescription Drug Benefit program.	
3.1.1F8	Language obligating the subcontractor to abide by all applicable Federal and State laws and regulations and CMS instructions.	
3.1.1F9	Language obligating the subcontractor to abide by State and Federal privacy and security requirements, including the confidentiality and security provisions stated in the regulations for the program at 42 CFR §423.136.	
3.1.1F10	Language ensuring that the subcontractor will make their books and other records available in accordance with 42 CFR §423.505(i)(2), which generally states these regulations give HHS, the Comptroller General, or their designees the right to inspect.	
3.1.1F11	Language stating that the subcontractor will ensure that beneficiaries are not held liable for fees that are the responsibility of the Applicant.	
3.1.1F12	Language stating that if the Applicant, upon becoming a Part D sponsor, delegates an activity or responsibility to the subcontractor, that such activity or responsibility may be revoked if CMS or the Part D sponsor determines the subcontractor has not performed satisfactorily. The subcontract may include remedies in lieu of revocation to address this requirement.	
3.1.1F13	Language specifying that the Applicant, upon becoming a Part D sponsor, will monitor the performance of the subcontractor on an ongoing basis.	
3.4A3	Provisions governing submitting claims to a real-time claims adjudication system. Note: Applicant may indicate for I/T/U pharmacies and for certain pharmacies that are allowed to submit claims in the X 12 format that these may be batch processed.	

3.4A4	Provisions governing providing access to negotiated prices.	
3.4A5	Provisions regarding charging/applying the correct cost-sharing amount, including that which applies to individuals qualifying for the low-income subsidy.	
3.4A6	Provisions governing informing the Part D enrollee at the point of sale (or at the point of delivery for mail order drugs) of the lowest-priced, generically equivalent drug, if one exists for the beneficiary's prescription, as well as any associated differential in price.	

Elements Specific to Long-Term Care Contracts

Note: CMS will release Long-Term Care Guidance in early March 2005. This document will contain an updated list of performance and service criteria as referenced in Item #1 of 3.4.5A. Applicants will be required to incorporate at a minimum, these criteria in any LTC pharmacy network contract. Applicant must list the criteria below, and then identify where the element is met in the contract.

	Performance/Service Criteria	**Citation**

Elements Specific to Indian Health Service, Indian Tribe and Tribal Organization, and Urban Indian Organization (I/T/U) Pharmacy Contracts

Note: Sections referenced are the provisions listed in the model I/T/U and IHS Addenda, located at http://www.cms.hhs.gov/pdps/ and http://www.cms.hhs.gov/aian/ The I/T/U Contracts must contain language consistent with the model tribal pharmacy and IHS addenda that address the following.

Item 3	The description of the provider.	
Item 4	Counting of costs paid for by provider toward any deductibles. ***[Cross check item #'s we didn't do that.]***	
Item 5	Persons eligible for services of the provider.	
Item 6	The applicability of certain Federal law.	
Item 7	The non-taxable status of the provider (only in contracts with tribal pharmacies)	
Item 8	Insurance and indemnification.	
Item 9	Applicability of state licensing law to provider's employees.	
Item 10 (Tribal only)	Provider eligibility for payments (only in contracts with tribal pharmacies).	
Item 11 (Tribal only & Item 10 (IHS)	Dispute resolution.	
Item 12 (Tribal) & Item 11 (IHS)	Federal law as the governing law.	
Item 13 (Tribal) & Item 12 (IHS)	The contract will apply to all pharmacies and dispensaries operated by the provider.	

Item 14 (Tribal) & Item 13 (his)	The contract will not affect the provider's acquisition of pharmaceuticals.	
Item 15 (Tribal) & Item 14 (IHS)	The provider's point of sale processing capabilities.	
Item 16 (Tribal) & Item 15 (IHS)	Claims processing.	
Item 17 (Tribal) & Item 16 (IHS)	Reasonable and appropriate payment rates.	
Item 18 (Tribal) & Item 17 (IHS)	Any information, outreach or enrollment materials prepared by the Applicant will be supplied at no cost to the provider.	
Item 19 (Tribal) & Item 18 (IHS)	The provider determines the hours of service for the pharmacies or dispensaries of the provider.	
Item 19 (Tribal only)	The contract will not be an official or implied endorsement by IHS or IHS employees (applicable only to IHS contract).	